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Proposed Re-evaluation Decision PRVD2011-12

Dimethoate

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario
K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

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Overview

Proposed Re-evaluation Decision for Dimethoate

After a thorough re-evaluation of the insecticide Dimethoate, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing continued registration for the sale and use of certain Dimethoate products in Canada.

An evaluation of available scientific information found that, under the proposed conditions of use:

- Certain uses of Dimethoate products have value in the food and crop industry and do not pose unacceptable risks to human health or the environment. As a condition of the continued registration for these particular Dimethoate uses, new risk-reduction measures must be included on the labels of certain Dimethoate products. In addition, registrants must submit additional confirmatory scientific information. Food residue data is required to confirm the assumptions in the dietary risk assessment and to verify and/or establish Maximum Residue Limits (MRLs) for current registered uses. To address the uncertainties around the formation of the oxygen analog (Omethoate) resulting from chlorination, a laboratory study investigating the effects of different chlorination methods at different pHs is required. These data may allow the PMRA to refine the aggregate dietary and drinking water assessment. Also, concurrent historical control data for vascular tumors for the Wistar rat in the 2-year chronic toxicity/oncogenicity study is required and an acute comparative cholinesterase study investigating the ability of metabolites of concern to inhibit brain cholinesterase following exposure is required.

- Some uses of Dimethoate are being proposed for phase out because the human health risks and/or risks to the environment do not meet current standards. These uses include the following: Application of Dimethoate to Douglas fir seed trees, Sitka spruce and spruce (woodland); application to structural sites; paint-on treatments to birch, roses and lilac. Also, application of Dimethoate with right-of-way sprayers and soil drench application to carnations cannot be supported.

In order to address some of the uncertainties in the occupational risk assessment, it is possible that additional data and use information could be submitted. The PMRA also welcomes feedback on the feasibility of proposed mitigation measures, the value of dimethoate for those uses where risk concerns have been identified and alternative control methods. Any relevant information provided during the proposed re-evaluation decision consultation period will be considered prior to a final decision.

The PMRA's pesticide re-evaluation program considers potential risks as well as the value of pesticide products to ensure they meet modern standards established to protect human health and the environment. In 1999, Health Canada announced in Re-evaluation Note REV99-01, *Re-evaluation of Organophosphate Pesticides*, that 27 organophosphate active ingredients, including Dimethoate, would be re-evaluated in Canada. Re-evaluation draws on data from registrants, published scientific reports, information from other regulatory agencies and any other relevant information available.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration.[1] The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of sensitive subpopulations in both humans (for example, children) and organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a re-evaluation decision on Dimethoate, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Re-evaluation Decision[4] on Dimethoate, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and the PMRA's response to these comments.

For more details on the information presented in this overview, please refer to the Science Evaluation section of this consultation document.

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[1] "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

[2] "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

[3] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

[4] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

What is Dimethoate?

Dimethoate is a broad spectrum organophosphate systemic insecticide and acaricide (BCPC, 2006). It is used to control a broad range of insects and mites on a variety of agricultural and non-agricultural sites and contributes to insecticide resistance management.

In Canada, dimethoate is registered to control a wide range of insect pests such as: aphids, beetles, weevils, grasshoppers, flies, leafhoppers, scale insects, thrips, moths and spider mites.

Dimethoate is used on both agricultural and non-agricultural sites which include feed, food, industrial oil seed and fibre, forestry and ornamental crops. It is also effective as a residual spray for fly control around farm buildings, animal quarters (empty), food processing plants (outdoors), garbage cans (outdoors), loading docks (outdoors), warehouses (outdoors), outdoor refuse areas, pastures and wasteland.

Dimethoate contributes to insecticide resistance management. Dimethoate plays an important role in delaying resistance when used in rotation with insecticidal active ingredients from different MoA (Mode of Action) groups. Based on Canadian pesticide labels, dimethoate is the only insecticide currently registered in Canada to control insect pests of Douglas fir (seed trees), Sitka spruce and spruce (woodland use). Furthermore, for some of the uses for which it is registered, there are few if any other effective registered alternatives.

Health Considerations

Can Approved Uses of Dimethoate affect Human Health?

Potential exposure to Dimethoate may occur through the diet or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur in animal testing and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and pregnant women). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no adverse effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when Dimethoate products are used according to label directions.

Dimethoate is highly toxic via the oral route and of low toxicity from dermal and inhalation routes of exposure. Dimethoate exhibits moderate eye and minimal dermal irritation in rabbits and is not a dermal sensitizer in guinea pigs under test conditions.

The target for Dimethoate is the nervous system including effects on brain acetylcholinesterase, an enzyme necessary for normal functioning of the nervous system. Overexposure may produce a variety of symptoms in animals and humans including nausea, dizziness, sweating, salivation, runny nose and watery eyes. This may progress to muscle twitching, weakness, tremor, incoordination, vomiting, abdominal cramps and diarrhea in more serious poisonings. Cholinesterase inhibition has been observed following oral, dermal and inhalation exposure. Young animals have been shown to be of similar sensitivity as adult animals to the cholinesterase inhibiting effects of Dimethoate.

Dimethoate was not found to be genotoxic or teratogenic. Based on the scientific evidence, Dimethoate is unlikely to pose a carcinogenic risk for humans. Following administration to pregnant and young rats, an increase in pup mortality has been observed. A clear association with the neurotoxic effects of Dimethoate has not been established. Reference doses selected in the risk assessment were based upon cholinesterase inhibition, an effect occurring at dose levels below those at which effects on pup survival have been observed. The risk assessment protects against all of the effects discussed by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food alone were not of concern. Aggregate dietary risks from food and drinking water may be of concern.

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

Human exposure to Dimethoate was estimated from residues in food and drinking water, including the most highly exposed sub-population (for example, infants and children 1-2 years old). Residues estimates in food were primary based on monitoring data from the Canadian Food Inspection Agency and the United States Department of Agriculture (USDA) Pesticide Data Program. Residues in drinking water were estimated using both modelling and monitoring data.

Based on the food contribution only, the acute and chronic exposure estimates for the general population were 37% and 6% of the reference doses, respectively. For the most sensitive population of children aged 1-2 years, the acute and chronic exposure estimates were 67% and 14% of the reference doses, respectively.

Aggregate chronic exposure (i.e. to Dimethoate exposure from food and drinking water) based on drinking water modelling data accounted for no more than 34% of the chronic reference dose for all population groups. As a result, chronic risks were not of concern to the Agency.

When using the drinking water modelling data, the acute aggregate exposure estimates for Dimethoate at the 99.9th percentile were 118% and 408% of the acute reference dose for the general population and for infants, respectively. When using drinking water monitoring data, the acute aggregate exposure estimates for Dimethoate at the 99.9th percentile were 56% and 108% of the acute reference dose for the general population and infants, respectively.

Details on the limitations and uncertainties associated with drinking water modelling and monitoring data can be found in the Science Evaluation of this consultation document (see Section 3.4.1).

The *Pest Control Products Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

MRLs for Dimethoate are currently specified for a wide range of commodities. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. The current MRLs for Dimethoate can be found in the Science Evaluation of this consultation document (see Section 8.1.1.4).

No modification of the MRLs were proposed during the course of the re-evaluation with the exception of withdrawing the MRLs for apples, cabbage, and spinach. In addition, the MRL for lettuce should be changed to lettuce (leaf). These changes are proposed as Dimethotate uses for apples, cabbage, spinach, and lettuce (head) have been voluntarily discontinued by the registrant in Canada and the United States.

Risks in Residential and Other Non-Occupational Environments

Residential and domestic risks are not of concern.

Potential risk to homeowners while using Dimethoate or from contact with commercially treated plants were mitigated through voluntary discontinuation of domestic class products and residential uses in 2004. Dimethoate can no longer be used in and around homes or other residential areas such as parks, school grounds and playing fields.

Aggregate risk from exposure incurred as a patron of a "Pick Your Own" orchard or berry facility is not of concern.

"Pick Your Own (PYO)" facilities are commercial farming operations that allow public access for harvesting in large-scale fields or orchards treated with commercially labelled Dimethoate products. Estimates of exposure that aggregate the dermal exposure incurred during harvest and the dietary exposure from consuming fresh fruit reach the target Margin of Exposure (MOE) for orchard and berry crops, and are therefore, not of concern.

Occupational Risks from Handling Dimethoate

The majority of occupational risks are not of concern provided additional mitigation measures are followed.

Occupational risk assessments consider exposure to workers who mix, load, and apply the pesticide. Most occupational risks are not of concern for commercial and agricultural scenarios provided additional protective measures are followed.

Based on the precautions and directions for use on the original product labels reviewed for this re-evaluation, risk estimates associated with certain mixing, loading and applying activities did not meet current standards and are of concern to the Agency. However, if mitigation measures including additional personal protective equipment, engineering controls or restrictions on the amount handled per day are used, the majority of uses reach target MOEs. These measures are needed to minimize potential exposure and protect worker's health.

Use scenarios that remain of concern include some forestry and ornamental uses (Douglas fir seed trees, Sitka spruce and spruce (woodland)); paint-on applications; right-of-way sprayer equipment; soil drench applications (carnations); and applications to structural sites. These uses cannot be supported due to occupational risk concerns, and therefore are proposed for discontinuation. To address refinements in the assumptions used in the occupational risk assessment, it is possible that additional data and use information could be submitted.

Occupational postapplication risks are of concern to workers performing high exposure activities.

Postapplication occupational risk assessments consider exposures to workers entering treated sites. When the proposed mitigation measures such as lengthened restricted-entry intervals (REIs) are considered, most occupational postapplication risk estimates meet the target MOE, and are not of concern to the Agency.

Based on the risk assessment, the risks to workers performing postapplication activities for Douglas fir, Sitka spruce and spruce (woodland), the restricted-entry intervals required to reach the target MOE range from 27 to 105 days, except for a few minor contact activities. These REIs are generally not considered to be agronomically feasible. In addition, these uses cannot be supported due to occupational handler risk concerns. For structural uses, there were no data available to adequately assess postapplication risk to workers.

Proposed protective measures to reduce worker exposure require consultation with user groups to determine their acceptability. Although the postapplication risk assessment for the commercial and agricultural scenarios identified risks of concern based on the current use pattern, the risk estimates include a number of uncertainties. The generation of additional data may refine the current risk assessment and would be required to potentially reduce the proposed REIs.

Environmental Considerations

What Happens When Dimethoate is Introduced Into the Environment?

Dimethoate poses a potential risk to terrestrial and aquatic organisms, therefore additional risk reduction measures need to be observed.

When Dimethoate is released into the environment some of it can be found in soil and surface water. However, Dimethoate is non-persistent with the main route of dissipation being biotransformation in soil and hydrolysis. Dimethoate is not expected to volatilize significantly. Laboratory studies indicate that Dimethoate is mobile in soil. However, there is no field evidence that the use of this insecticide will result in groundwater contamination, most probably due to the rapid microbiological breakdown of Dimethoate in soil.

Dimethoate poses risk to terrestrial and aquatic organisms. In order to minimize the potential exposure, strips of land between the agricultural field and the aquatic areas will be left unsprayed. The width of these buffer zones will be specified on the product label. Water monitoring data indicate that Dimethoate can occur in runoff.

Value Considerations

In Canada, Dimethoate is registered to control a wide range of insect pests such as: aphids, beetles, weevils, grasshoppers, flies, leafhoppers, scale insects, thrips, moths and spider mites.

Dimethoate is used on both agricultural and non-agricultural sites which include feed, food, industrial oil seed and fibre, forestry and ornamental crops. It is also effective as residual spray for fly control around farm buildings, animal quarters (empty), food processing plants (outdoor use), garbage cans (outdoor use), loading docks (outdoor use), warehouses (outdoor), outdoor refuse areas, pastures and wasteland.

Dimethoate is important in the resistance management of pests. Furthermore, for some of the uses for which it is registered, there are few if any other effective registered alternatives.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

Risk-reduction measures are being proposed to address potential risks identified in this assessment. These measures, in addition to those already identified on existing Dimethoate product labels, are designed to further protect human health and the environment. The following key risk-reduction measures are being proposed.

Additional Key Risk-Reduction Measures

Human Health

After consideration of all other possible mitigation measures, the following uses cannot be supported due to occupational risk concerns. These uses should be removed from all Dimethoate labels. To address refinements in the assumptions used in the occupational risk assessment, it is possible that additional data and use information could be submitted.

- Application to Douglas fir seed trees, Sitka spruce and spruce (woodland).
- Application to structural sites
- Paint-on treatments to birch, roses and lilac
- Application with right-of-way sprayers
- Soil drench application to carnations

For all other uses, to protect mixer/loader/applicators using commercial products, additional personal protective equipment, engineering controls and restrictions on amount of active handled per day are required.

For all other uses, to protect workers entering treated sites: restrictions on the number of applications, increased application intervals and restricted-entry intervals are to be added to product labels.

Precautionary statements to avoid drift to areas of human habitation or areas of human activity are to be added to product labels.

To reduce aggregate dietary and drinking water exposure and risk, increase in pre-harvest intervals (PHIs) and reduction of maximum rates are to be implemented.

Environment

Changes to label statements, including precautionary statements and buffer zones for non-target aquatic habitats are required as a result of the environmental risk assessment.

To reduce the potential for Dimethoate of run off to adjacent aquatic habitats changes to label statements, to include precautionary statements for sites with characteristics that may be conducive to runoff and when heavy rain is forecasted.

What Additional Scientific Information is being Requested?

Human Health

The following studies are required under section 12 of the *Pest Control Products Act*:

- Food residue data to confirm the assumptions in the dietary risk assessment and to verify and/or establish MRLs for current registered uses.
- To address the uncertainties around the formation of the oxygen analog (Omethoate) resulting from chlorination, a laboratory study investigating the effects of different chlorination methods at different pHs is required. These data may allow the PMRA to refine the aggregate dietary and drinking water assessment.
- Concurrent historical control data for vascular tumors for the Wistar rat in the 2-year chronic toxicity/oncogenicity study (DACO 4.4.4).
- Acute comparative cholinesterase study investigating the ability of metabolites of concern to inhibit brain cholinesterase following exposure (DACO 4.5.12).

Environment

There are no outstanding data requirements with regard to environment.

Next Steps

Before making a re-evaluation decision on Dimethoate, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document). The PMRA will then publish a Re-evaluation Decision, which will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

At the time of the re-evaluation decision, registrants will be asked to submit supplementary information to confirm or refine the current risk assessment, including:

Other Information

At the time that the re-evaluation decision is made, the PMRA will publish an Evaluation Report on Dimethoate in the context of this re-evaluation decision (based on the Science Evaluation of this consultation document). In addition, the test data on which the decision is based will also be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Once all organophosphate pesticides have been re-evaluated, a cumulative risk assessment will be conducted, which will consider potential exposure to all chemicals causing toxicity in the same manner. The results of the cumulative risk assessment may affect any previous re-evaluation decision.

Science Evaluation

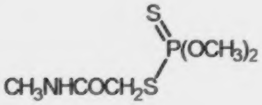
1.0 Introduction

Dimethoate is one of the 27 organophosphate pesticides subject to re-evaluation in Canada as announced in the Re-evaluation Note REV99-01, *Re-evaluation of Organophosphate Pesticides*. Dimethoate is a broad spectrum organophosphate insecticide belonging to Resistance Management Mode of Action (MoA) Group 1B, which inhibits the enzyme acetylcholinesterase, interrupting the transmission of nerve impulses in insects. It works by systemic and contact action. Some of the familiar trademarks of Dimethoate are “Cygon”, “Di-Thoate” and “Lagon”.

In Canada, Dimethoate is registered for use on a wide variety of feed, food, forestry, industrial oil seed and fibre, ornamental crops and non-agricultural sites to control a wide range of insects and mites such as: aphids, beetles, weevils, grasshoppers, flies, leafhoppers, scale insects, thrips, moths, and spider mites. Dimethoate is also used for the control of flies in dairy barns, poultry houses and other farm buildings.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

Identity of the Technical Grade Active Ingredient

Common name	Dimethoate
Function	Insecticide, acaricide
Chemical Family	Organophosphate
Chemical name	
	1 International Union of Pure and Applied Chemistry (IUPAC)O,O-dimethyl S-methylcarbamoylmethyl phosphorodithioate
	2 Chemical Abstracts Service (CAS)O,O-dimethyl S-[2-(methylamino)-2-oxoethyl] phosphorodithioate
CAS Registry Number	60-50-1
Molecular Formula	$C_5H_{12}NO_3PS_2$
Structural Formula	
Molecular Weight	229.2
Purity of the Technical Grade Active Ingredient	98.4% nominal (96.0–99.8%)
Registration Number	19067

2.1 Identity of relevant impurities of human health or environmental concern:

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the *Canada Gazette*, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the product.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Value[1]	Interpretation
Vapour pressure at 25°C	0.25 mPa	not likely to volatilize from moist soils or water surfaces
Henry's law	1.42×10^{-6} Pa m^3 mol^{-1}	
Ultraviolet (UV)/visible spectrum	Not expected to absorb at $\lambda > 300$ nm	Unlikely to undergo direct phototransformation
Solubility in water at 25°C	23.3 g/L (pH 5) 23.3 g/L (pH 5) 25.0 g/L (pH 9)	very soluble in water
n-Octanol–water partition coefficient at (log K_{ow})	Log $K_{ow} = 0.704$	not likely to bioaccumulate
Dissociation constant	p$Ka = 2.0$ at 20°C	hydrolyses moderately under acidic and neutral conditions, easily hydrolyses under basic conditions

[1] The e-Pesticide Manual ver.3.1; ed. British Crop Protection Council, 2004

2.3 Description of Registered Dimethoate Uses

Appendix I list all Dimethoate products that are registered under the authority of the *Pest Control Products Act*. Appendix II lists all the uses for which Dimethoate is presently registered. All uses were supported by the registrant at the time of re-evaluation initiation and were therefore considered in the health and environmental risk assessments of Dimethoate. Also presented is whether the use was added through the PMRA Minor Use Program. While currently supported by the registrant, the data supporting the use was originally generated by a user group.

The registrant is supporting the use of dimethoate on the following sites, which are included in the risk assessments:

Feed crops:	alfalfa, barley, oats, wheat, canary grass (seed production), canola (rapeseed), flax, clovers, rye, potato, pea (field), soybean, turnip greens, forage grasses, safflower, pastures and wastelands.
Food crops:	asparagus, barley, beans, beet, beet greens, blueberry (low and high bush), broccoli, brussel sprouts, cauliflower, canola, celery, cherry (sour and sweet), chicory, Chinese broccoli, eggplant, filbert, flax, grains, hazelnut, kale, lettuce (other than head lettuce), oats, Pak choi, peas (field and canning), peach (non-bearing), pear, pepper, potato, rye, safflower, soybean, strawberry, Swiss chard, tomato (field), turnip greens and wheat (durum, spring and winter).
Industrial oil seed and fibre crops:	canola (rapeseed), flax, and soybean.
Forestry sites:	balsam fir, Christmas trees (balsam fir, spruce, hemlock, mugho pine, red pine, Scots pine), Douglas fir (seed tree), hemlock, larch, pine (mugho, Scots, red), spruce, spruce (woodland use) and Sitka spruce.
Ornamental crops:	arborvitae, azalea, balsam fir, birch, boxwood, camellia, carnation, cedar, day lily, Christmas trees (balsam fir, spruce, hemlock, mugho pine, red pine, Scots pine), Douglas fir (seed tree), *Euonymus*, gardenia, gerbera, gladiolus, hemlock, holly (American and English), iris, juniper, larch, pine (mugho, Scots and red), spruce, *Taxus* (yew), lilac (*Syringa* spp.), oak, Sitka spruce, poinsettia and rose.
Structural:	in and around farm buildings, such as calf barns, dairy barns, hog pens, poultry houses and other associated buildings, animal quarters (empty), food processing plants (outdoor use), garbage cans (outdoor use), loading docks (outdoor use), warehouses (outdoor), and outdoor refuse areas.

3.0 Impact on Human and Animal Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels where no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species. The health effects noted here were observed in animals at dose levels at least

100-fold (often much higher) above levels to which humans are normally exposed through use of products containing this chemical.

3.1 Toxicology Summary

Hazard Identification

The current risk assessment is based primarily upon studies submitted by the registrant, although the hazard profile has been supplemented with data identified in international risk assessments and supporting documents. The toxicology database confirms that Dimethoate has anticholinesterase activity in various species and produces typical toxic signs of the organophosphate (OP) class of chemicals.

With oral exposure in rats, Dimethoate was readily absorbed and extensively metabolized. The metabolites were rapidly eliminated mainly in the urine. A small amount of unchanged parent compound was also detected in the urine. Excretion profiles were similar for the intravenous and oral routes and independent of dose or sex. Accumulation in the tissues is not likely. The metabolism of Dimethoate proceeds via hydrolytic and oxidative pathways. Major identified urinary metabolites included Dimethoate carboxylic acid (major), dimethylthiophosphoric acid and dimethyldithiophosphate. Omethoate, a minor metabolite, is the oxon analogue of Dimethoate and the primary cause of cholinesterase inhibition following Dimethoate exposure.

In acute toxicity studies, Dimethoate was moderately or highly toxic to rats, and highly toxic to mice by the oral route, and of low toxicity to rats or rabbits by the dermal or inhalation route. Acute signs of intoxication were those typical of organophosphates: muscular fibrillation, salivation, lacrimation, urinary incontinence, diarrhea, respiratory distress, prostration, gasping, coma and death. Dimethoate was moderately irritating to eyes and minimally irritating to skin of rabbits, but was not a skin sensitizer in guinea pigs.

Subchronic and/or chronic dietary studies showed that the inhibition of acetylcholinesterase was the most sensitive indicator of toxicity with the brain and erythrocyte cholinesterase found to be first affected in most cases in rat and dog studies. Depressed weight gain and food consumption, and increased liver weights were occasionally seen at higher dose levels. Rats appeared to be slightly more sensitive than other species (i.e. mouse and dog) based on NOAEL/LOAEL values. No pronounced sex differences were apparent in the available database except a few studies in rats where females were more sensitive than males in the cholinesterase inhibition. A comparison of data from rat studies of different durations shows increased toxicity with repeat-dose exposure compared to a single exposure, however differing methods of exposure (gavage versus dietary) confound the issue.

Short-term dermal toxicity studies in rats were conducted with Dimethoate formulations. The formulations contained similar major components as many currently registered products, and thus, were considered relevant. The inhibition of cholinesterase activities (brain, erythrocyte and plasma) was also identified as the most sensitive endpoint in the short-term dermal toxicity assay.

Dimethoate was not genotoxic in extensive *in vitro* and *in vivo* genotoxicity assays except for an *in vitro* unscheduled DNA synthesis (UDS) assay at cytotoxic levels (negative *in vivo* UDS). No treatment-related tumorigenicity was evident in mice following chronic dosing with Dimethoate. However, the rat study showed an increased incidence of vascular tumors (combined hemangiomas and hemangiosarcoma in the spleen, lymph node and skin) in treated male Wistar rats at doses tolerated by the animals, but the increase did not show a clear dose-response relationship. These tumors did not affect mortality (all were reported at final sacrifice) and achieved only marginal statistical significance. Although other regulatory authorities have indicated that the control incidence was lower than expected, the lack of concurrent historical data did not permit verification of this. Additional points considered in the weight of evidence were i) the increased tumors were observed in one sex only, ii) the increased tumors were observed in one species only, iii) Dimethoate was largely non-genotoxic, iv) carcinogenicity studies with the metabolite, Omethoate, did not show an increased tumor response, and v) organophosphates as a class do not show evidence of tumorigenicity of the vascular system. Consequently, based on the scientific evidence, Dimethoate is unlikely to pose a carcinogenic risk for humans.

There was no evidence of teratogenicity in rats or rabbits, and no increased sensitivity of the fetus in the prenatal developmental studies with Dimethoate. While cholinesterase measurements were lacking in most maternal animals and fetuses in the prenatal developmental studies, a comparative cholinesterase study did not show increased sensitivity of the fetus to cholinesterase inhibition. No increased sensitivity of the offspring was evident in the reproduction studies. Parental toxicity included cholinesterase inhibition (brain, erythrocytes and plasma). Decreased fertility (both generations) was observed in one study but not in a second study; however, the latter study showed increased pathological findings in the epididymis and prostate. Offspring effects included depressed brain cholinesterase and weight gain in both studies at comparable doses and decreased litter size and increased pup mortality during lactation in a single study. The doses causing toxicity to the pups and decreased reproductive performance in adult animals were several-fold higher (~4x) than those causing cholinesterase inhibition in the adult animals.

Dimethoate did not cause delayed neurotoxicity in hens following acute exposure. No treatment-related neuropathy or brain morphological changes was evident in the database. Neurotoxicity studies in rats confirmed the sensitivity of cholinesterase inhibition as a pivotal endpoint. The developmental neurotoxicity study in rats resulted in no adverse maternal or reproductive toxicity, but did result in a dose-related increase in pup deaths. At the lowest dose showing an effect on pup mortality, a comparable level of brain cholinesterase inhibition (10-13%) was observed between subpopulations (pregnant dams, fetuses, 4-day old pups, 21-day old pups and adult rats exposed for 11- days) in a comparative cholinesterase study. A cross-fostering gavage study of Dimethoate in rats showed that pup mortality ensued from either pre-natal exposure, post-natal exposure or combined pre- and post-natal exposure. The cross-fostering study did not resolve whether the pup mortality was due to maternal neglect. The EPA in collaboration with the PMRA developed a science issue paper entitled: *Dimethoate: Issues Related to the Hazard and Dose-response Assessment* (USEPA, 2004) which was reviewed by a USEPA Scientific Advisory Panel (SAP) in December 2004. The panel provided comments regarding the interpretation of cholinesterase inhibition in juvenile and adult rats along with pup mortality from the DNT study and related special studies. The panel agreed that while the underlying cause of pup mortality could not be ascertained from the data, the use of brain cholinesterase inhibition as the critical effect for risk assessment would be protective of pup death (FIFRA SAP, 2005).

Reference doses have been set for Dimethoate based on the most sensitive indicator of toxicity, namely brain cholinesterase inhibition. Benchmark dose (BMD) modelling was undertaken to better reflect the point of departure for the brain cholinesterase inhibition responses as well as that of pup mortality. The dataset for BMD analyses was considered robust in that the similarity of protocols of several studies yielded replicate information. Further, robust dose-response curves were attainable from studies of varying modes of administration and durations. BMD analysis was undertaken using an exponential dose-response model. An increase of 5% above background (BMD_5) was considered the smallest detectable change for pup mortality. For brain cholinesterase inhibition, a BMD_{10} was the limit of sensitivity for detecting a statistically significant decrease in cholinesterase activity. The EPA SAP supported the BMD analyses. The BMD analyses for cholinesterase inhibition showed similar dose-response curves and BMD_{10} values for all ages following similar exposure durations. The BMD analyses also indicates that use of the lower 95% confidence limit ($BMDL_{10}$) for brain cholinesterase inhibition would be protective of the $BMDL_5$ for pup mortality.

Omethoate is an active metabolite which may form from the oxidation of Dimethoate in mammals, plants and as an environmental degradate. The available toxicology data indicated that it is readily absorbed from the gastrointestinal tract and quickly eliminated (primarily in the urine) with minimal tissue retention. Acute toxicity studies indicated that Omethoate is a potential skin sensitizer and is much more toxic than Dimethoate by oral, dermal and inhalation routes of exposure based on LD/LC_{50} values. Acute signs of toxicity induced by Omethoate were consistent with cholinesterase inhibition. No apparent delayed neurotoxicity was evident in hens following acute exposure.

The available toxicology profile of Omethoate after subchronic or chronic exposure was similar to that of Dimethoate, but showed a higher potency in anticholinesterase activity (brain, erythrocyte and plasma) in various species tested (i.e. rat, rabbit, dog), of which, the brain cholinesterase was generally the most sensitive indicator of toxicity. No carcinogenicity was evident in rats and mice following chronic dosing. Genotoxicity assays were negative, except for positive results observed in an *in vivo* mouse spot test, a gene mutation assay at very high dose levels and in *in vitro* assays for DNA repair and sister chromatid exchange. No effects were observed in *in vivo* assays of DNA repair and sister chromatid exchange.

Omethoate exposure showed no evidence of teratogenicity in rats. In developmental toxicity studies in rabbits, an increased incidence of arthrogryposis was reported in Himalayan rabbits but not in New Zealand White rabbits. In the absence of historical control data on Himalayan rabbits, it is not certain whether the increase was due to the treatment. Other developmental effects included decreased fetal weight (Long Evans rats) and increased resorptions (Long Evans rats and Himalayan rabbits), but no developmental effects were reported in Wistar rats or New Zealand White rabbits. The development effects were all reported in the presence of maternal toxicity (decreased maternal weight gain or decreased cholinesterase activity) and thus would likely be related to maternal toxicity. No increased sensitivity of the fetuses was evident following *in utero* exposure to Omethoate. However, cholinesterase data were lacking in most maternal animals and fetuses precluding a more refined analysis of the sensitivity issue.

A 2-generation reproductive toxicity study of Omethoate in drinking water in rats showed no increased sensitivity of the young following *in utero* or postnatal exposure; the offspring and reproductive effects were observed only in the presence of parental toxicity. Offspring effects included increased pup death and decreased pup weight gain. Reproductive effects included decreased fertility and increased epididymal vacuolation and implantation loss. Parental effects included decreased brain and erythrocyte cholinesterase activity. However, a 3-generation reproductive study in the diet in rats showed an increased incidence of pup death in the absence of parental toxicity, but cholinesterase activity (the most sensitive indicator of Omethoate toxicity) was not assessed in this study and thus precluded a more refined analysis of the sensitivity issue.

The available data showed that Omethoate (a Dimethoate metabolite) is a more potent cholinesterase inhibitor than Dimethoate. To account for this increased toxicity, toxicity adjustment factors (TAFs) were calculated based on ratios of Dimethoate and Omethoate benchmark doses. TAFs are used to convert exposures of Omethoate into exposure equivalents of Dimethoate. Factors were derived from female rat brain cholinesterase BMD_{10} responses.

A TAF of 12 was applied to residues of Omethoate in the acute dietary and short-term dermal occupational exposure assessments. A TAF of 3 was applied to residues of Omethoate in the chronic dietary and intermediate-term dermal occupational exposure assessments. As the study selected for the inhalation risk assessment of Dimethoate used Omethoate as the test substance, no TAF for inhalation exposure to Omethoate is required.

Some potential plant and/or environmental metabolites of Dimethoate may possess cholinesterase inhibition activity. Three metabolites that are structurally similar to Omethoate; O-desmethyl Omethoate, O-desmethyl Omethoate carboxylic acid and O-desmethyl isoDimethoate, have shown less cholinesterase inhibiting potential than Dimethoate with acute exposure. In addition, there is evidence to suggest that Dimethoate carboxylic acid, an animal metabolite, may be present in eggs and milk at low levels. Data relating to the ability of the latter metabolite to cause cholinesterase inhibition has not been identified. Limited data indicates that it is unlikely acute exposure to these metabolites of Dimethoate (other than Omethoate) will make a significant contribution to potential risk. However, confirmatory data measuring the cholinesterase inhibiting potential of these metabolites of concern following acute exposure is required.

3.1.1 *Pest Control Products Act* Hazard Consideration

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects. This factor should take into account potential pre- and post-natal toxicity and completeness of the data with respect to the exposure of, and toxicity to, infants and children. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicity database, no additional studies are required at this time. Extensive data were available on Dimethoate including prenatal developmental toxicity studies in rats and rabbits, two multi-generation reproduction studies, a developmental neurotoxicity study, a comparative cholinesterase study (examining fetuses, pups, pregnant animals and adult animals) and a special cross-fostering study. Acceptable Omethoate data included two rat developmental toxicity studies, two rabbit developmental toxicity studies and a multi-generation reproduction study.

With respect to potential pre-and post-natal toxicity, prenatal developmental toxicity studies in rats and rabbits provided no indication of increased susceptibility of rat or rabbit fetuses to *in utero* exposure to Dimethoate or Omethoate. Similarly, there was no indication of increased susceptibility in the offspring compared to parental animals in the reproduction studies. Based on the BMD analysis of the cholinesterase inhibition data, juvenile animals exhibit similar sensitivity as adult animals following similar exposure durations to Dimethoate. An increase in pup mortality in repeat-dosing studies was observed with the most sensitive study being the developmental neurotoxicity study. Although no clear association could be made between a specific level of brain cholinesterase inhibition and an increase in pup death, results of the BMD analyses support the conclusion that protection against brain cholinesterase inhibition will also result in protection against increased pup mortality. This position was supported by a USEPA FIFRA Scientific Advisory Panel (2004). On the basis of this information, the 10-fold *Pest Control Products Act* factor has been reduced to 1-fold.

3.2 Occupational and Non-Occupational Risk Assessment

Occupational and non-occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies to calculate a margin of exposure (MOE). This calculated MOE is compared to a target MOE incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects. However, MOEs less than the target MOE require measures to mitigate (reduce) risk.

3.2.1 Toxicology Endpoint Selection for Occupational and Bystander Risk Assessment

3.2.1.1 Short- and Intermediate-term Dermal Risk Assessment

Short-term (1-30 days) and Intermediate-term (1-6 months) Occupational Dermal Risk Assessment

For dermal risk assessment, a $BMDL_{10}$ of 19 mg/kg bw/day from a 28-day repeat-dose dermal study in rats was selected in which brain cholinesterase was inhibited but there was no other systemic or dermal toxicity. As the use of brain cholinesterase as a critical endpoint in risk assessment was found to be protective of pup mortality via oral exposure, it was assumed that this determination was also valid for other routes of exposure. Furthermore, the $BMDL_{10}$ of the 28-day study was considered to be relevant to short- and intermediate-term exposure since repeat-dose oral studies did not show a significant effect of dose duration on cholinesterase activity. A target MOE of 100 is required to account for interspecies extrapolation (10-fold) and intraspecies variability (10-fold).

For Omethoate residues, a toxicity adjustment factor of 12 is applied to this exposure scenario to account for increased toxicity of the metabolite following acute exposure.

3.2.1.2 Short- and Intermediate-term Inhalation Risk Assessment

Short-term (1-30 days) and Intermediate-term (1-6 months) Occupational Inhalation Risk Assessment

For inhalation risk assessment, a repeat-dose study was not available for Dimethoate. A 21-day repeat-dose inhalation study in rats was available with Dimethoate's more toxic metabolite, Omethoate. The $BMCL_{10}$ of 0.00038 mg/L (~0.1 mg/kg bw/day) for Omethoate-induced brain cholinesterase inhibition was considered a conservative surrogate for the Dimethoate assessment. As with the other routes of exposure, it was assumed that use of the brain cholinesterase endpoint was protective of pup mortality. Furthermore, the $BMDL_{10}$ of the 21-day study was considered to be relevant to short- and intermediate-term exposure since repeat-dose oral studies did not show a significant effect of dose duration on cholinesterase activity. A target MOE of 100 is required to account for interspecies extrapolation (10-fold) and intraspecies variability (10-fold).

3.2.1.3 Cancer Risk Assessment

The weight of evidence indicates that Dimethoate is unlikely to be a human carcinogen and therefore a cancer risk assessment was not required.

3.2.2 Occupational Exposure and Risk Assessment

Workers can be exposed to Dimethoate through mixing, loading or applying the pesticide, and when entering a treated site to conduct activities such as scouting and/or the handling of treated crops.

3.2.2.1 Mixer, Loader and Applicator Exposure and Risk Assessment

There are potential exposures to mixers, loaders, and applicators. The following supported uses were assessed:

- Mixing/loading of liquid (solutions and emulsifiable concentrate) formulations.
- Aerial application to hemlock, spruce, Balsam fir, canola, flax, safflower, soybeans, alfalfa, clover, canary seed and grass, forage crops, grains, pastures, wastelands, cereals, beans, peas and blueberries.
- Groundboom application to canola, flax, safflower, soybeans, alfalfa, clover, canary seed and grass, forage crops, grains, wastelands, pastures, beans, asparagus, bok choi, brussel sprouts, Chinese broccoli, chicory, peppers, broccoli, cauliflower, cereals, beet greens, turnip greens, kale, lettuce, Swiss chard, beets, celery, eggplant, peas, potatoes, tomatoes, blueberries and strawberries.
- Handwand or backpack sprayer application to birch, boxwood, Christmas trees, cedar, pine, oak, Douglas fir seed trees, hemlock, spruce, Balsam fir, Sitka spruce, spruce (woodland), arborvitae, juniper, taxus (yew), euonymus, azaleas, camellias, carnations, gardenias, gerberas, gladioli, poinsettas, roses, day lilies, irises, holly, larch, lilac and structural sites.
- Airblast application to birch, boxwood, Christmas trees, cedar, pine, oak, Douglas fir seed trees, hemlock, spruce, Balsam fir, Sitka spruce, spruce (woodland), blueberries, cherries, hazelnuts (filberts), peaches, pears, arborvitae, juniper, taxus (yew), euonymus, holly, larch and lilac.
- Right-of-way sprayer application to wastelands, pastures and forage grasses.
- Paintbrush application to birch, roses and lilac.
- Soil drench or injection application to birch, camellias and carnations.
- Chemigation to strawberries.

Due to the number of agricultural applications per year (ranging from 1 to 6), exposure is likely to be short- to intermediate-term (i.e. up to several months) in duration. The PMRA estimated handler exposure based on different levels of personal protective equipment:

A. Maximum personal protective equipment (PPE) with a respirator:
Chemical resistant coveralls over a single layer (long sleeved shirt and long pants) with chemical resistant gloves and a suitable respirator with open cab and open mixing/loading.

B. Engineering controls:
Closed cab application for groundboom and airblast equipment with applicators wearing cotton coveralls over a single layer. Closed mixing and loading of liquids for aerial application with workers wearing cotton coveralls over a single layer.

C. Maximum PPE with a respirator and chemical resistant headgear for open cab airblast applicators:
In scenarios where closed cab application equipment may not be feasible (i.e. airblast application in orchards), maximum PPE, with chemical resistant headgear, chemical resistant gloves, plus a suitable respirator is considered as an alternative. Chemical resistant head gear includes so'westers, or large brimmed, water-proof hats, and hoods with sufficient neck protection.

No acceptable chemical-specific handler exposure data was submitted for Dimethoate; therefore, dermal and inhalation exposures were estimated using data from the Pesticide Handlers Exposure Database (PHED), Version 1.1. PHED Version 1.1 is a compilation of generic mixer/loader applicator passive dosimetry data with associated software that facilitates the generation of scenario-specific exposure estimates based on formulation type, application equipment, mix/load systems and level of PPE.

In most cases, PHED did not contain appropriate data sets to estimate exposure to workers wearing coveralls or chemical-resistant coveralls. This was estimated by incorporating, where applicable, a 75% clothing protection factor for cotton coveralls, a 90% clothing protection factor for chemical-resistant coveralls and a 90% protection factor for a respirator into the unit exposure data. Similarly, a 90% protection factor was applied to head and neck dermal unit exposure values for chemical-resistant headgear.

Inhalation exposures were based on light inhalation rates (17 LPM) except for backpack applicator scenarios which were based on moderate inhalation rates (27 LPM).

Mixer/loader/applicator exposure estimates are based on the best available data at this time. Negligible Omethoate exposure is expected to occur to mixer/loader/applicators, thus Omethoate exposure was not considered in the assessment. The generation of exposure data representative of modern application equipment and engineering controls may potentially refine the risk assessment. Biological monitoring data could also further refine the assessment.

3.2.2.1.1 Occupational Exposure Risk Estimates

Occupational risk estimates associated with mixing, loading, and applying for agricultural uses meet the targets for the majority of uses provided PPE and/or engineering controls are used as summarized in Appendix IV. Table 1, Table 2 and Table 3 of Appendix VI summarizes the calculated risks for mixer/loaders and applicators.

Calculated MOEs were below the target MOE of 100 with maximum feasible personal protective equipment and/or engineering controls for the following uses:

- Douglas fir seed trees, Sitka spruce, spruce (woodland) for application with airblast and high pressure handwands.
- Paint-on treatments (lilac, roses, birch); soil drench application (carnations).
- Application with right-of-way sprayer equipment.
- Application to structural sites (i.e. farm buildings, loading docks, etc.) with high pressure handwands.

Calculated combined MOEs also marginally failed to meet the target MOE of 100 with maximum PPE and a respirator for application with high pressure handwands to: Christmas trees (Balsam fir, hemlock, pine), cedar, oak, arborvitae, juniper, taxus, yew, euonymus and larch. Restricting the amount of active ingredient handled per day to 2.8 kg per person (for example approximately 2950 L at a rate of 0.96 g a.i./L) when applying by handheld equipment is a potentially feasible mitigation measure for these scenarios. The calculated dermal and inhalation MOEs will meet the target MOE of 100 provided that this additional mitigation measure is adhered to during mixing/loading and application.

3.2.2.2 Postapplication Worker Exposure and Risk Assessment

The postapplication occupational risk assessment considered exposures to workers who re-enter treated sites to conduct agronomic activities involving foliar contact (for example, pruning, thinning, harvesting, or scouting). Based on the Dimethoate use pattern, there is potential for short- to intermediate-term (>1 day to 6 months) postapplication exposure for workers.

For workers entering agricultural crops which have been treated with Dimethoate, there is potential for postapplication dermal exposure to both residues of Dimethoate and residues of the more toxic metabolite Omethoate, which forms during environmental degradation.

Potential exposure to postapplication workers was estimated using activity specific transfer coefficients (TC) and dislodgeable foliar residue (DFR) values. The TC is a measure of the relationship between exposure and DFRs for individuals engaged in a specific activity, and is calculated from data generated in field exposure studies.

All submitted chemical-specific DFR studies were considered, and three acceptable DFR studies were used to determine residue dissipation and foliar residues in the assessment of worker postapplication exposure. These studies were performed on apple trees, tomato plants and leaf lettuce. All studies reported residues of both the parent compound, Dimethoate, and the degradation product, Omethoate. When calculating risk, to account for the increased toxicity of Omethoate, a toxicity adjustment factor (TAF) was used to convert exposures of Omethoate into equivalent exposures of Dimethoate. Given that the studies were conducted using two applications per season, only short-term postapplication exposure was considered. Thus, the short-term TAF of 12 was applied to Omethoate residues to calculate total Dimethoate residue equivalents. The short-term postapplication assessment will cover off any intermediate-term risks as the short-term TAF for Omethoate is higher than the intermediate-term TAF. The following equation was used to calculate total DFR:

Total Dislodgeable Foliar Residues (DFR) = Dimethoate DFR + 12x Omethoate DFR

Based on a comparison of foliage type and application equipment, the apple, tomato plant, and lettuce DFR studies were used to estimate DFRs for all Canadian crops, trees and ornamentals. From each crop study, data from one site was selected for use based on a comparison of climatic conditions, dissipation rates and peak DFR values. See Table 3.2.2.2 for a list of which crop study and site data was used to estimate residues on registered Canadian agricultural crops and ornamentals. All crops were assessed using two applications and application intervals of 7 to 10 days as described in the studies and the calculated DFR data was normalized to maximum Canadian application rates assuming a linear relationship. None of the DFR studies were considered to be representative of structural uses for fly control (around garbage cans, refuse areas, farm buildings, etc.).

Due to the limited number of acceptable DFR studies available to the PMRA for the postapplication risk assessment, the extrapolation of tomato, lettuce and apple data to a wide variety of crops was required. Since the studies available are not necessarily a good representation of some Canadian crops, this extrapolation represents an area of uncertainty in the postapplication assessment.

Table 3.2.2.2 Available DFR Studies and their Application to Canadian Crops

Study (Site)	**Applications**		**Initial Deposition at Day 0[a] (%)**		**Daily Dissipation[b] (%)**		**Canadian Crops**
	Frequency	**Interval (days)**	**DIM**	**OM**	**DIM**	**OM**	
Apple Study[c] (Washington)	2	10	16.6	0.16	7.36	2	Spruce, birch, boxwood, cedar, oak, Christmas trees, pine, Douglas fir seed trees, hemlock, balsam fir, Sitka spruce, cherries (sweet and sour), peaches, pears, filberts (hazelnuts), blueberries, arborvitae, juniper, taxus, euonymus, holly, lilac, larch

Study (Site)	Applications		Initial Deposition at Day 0[a] (%)		Daily Dissipation[b] (%)		Canadian Crops
	Frequency	Interval (days)	DIM	OM	DIM	OM	
Tomato Study[d] (California)	2	7	5.71	0.44	28.3	7.88	Canola, flax, alfalfa, clover (sweet, red, alsike), canary seed and grass, forage crops, pastures, wastelands, grains, cereals (barley, oat, wheat and rye), safflower, soybeans, asparagus, beans, broccoli, cauliflower, eggplant, peas, brussel sprouts, peppers, potatoes, tomatoes, strawberries, azaleas, camellias, carnations, gardenias, gerberas, gladioli, pointsettas, roses, day lilies, irises
			Actual study data values used[d]				
Lettuce Study[c] (California)	2	7	18.4	1.12	30	9.46	Turnip greens, kale, lettuce, beet greens, Swiss chard, bok choi, chicory, Chinese broccoli, beets, celery

DIM = Dimethoate, OM = Omethoate

[a] Initial deposition is considered to be the percentage of the application rate (kilograms active ingredient per hectare) that is dislodgeable.

[b] Daily dissipation is the rate at which the dislodgeable foliar residue dissipates; derived from the slope of the DFR curve (ln of dislodgeable residue vs. time).

[c] As r^2 values of the ln-transformed predicted DFR curve were > 0.85, DFR values were calculated from predicted DFR dissipation curves using the following equation: $DFR_t = DFR_0 * e^{(t*K)}$. Where DFR_t = DFR at day t; DFR_0= predicted DFR at day 0; t = Day after treatment; e = 2.71828; K = the slope of the ln of the transferable residue vs. time.

[d] r^2 values for the Omethoate ln-transformed predicted DFR curve were < 0.85, therefore actual study data was used in the assessment.

For workers entering a treated site, restricted-entry intervals (REIs) are calculated to determine the minimum length of time required before individuals can safely enter after application. An REI is the duration of time that must elapse before residues decline to a level where performance of a specific activity results in exposures above the target MOE (i.e. >100 for short-to-intermediate-term dermal exposure). The postapplication exposure and risk assessments are summarized in Table 4 of Appendix VI. No data exists to adequately assess postapplication exposure from structural sites.

The assessments could be refined and uncertainties reduced with the following data:

- enhanced information on the Dimethoate use pattern, including typical rates and number of applications per season;
- survey information on critical worker activities that typically take place for each crop during the use season, and the timing of these activities with respect to crop growth and applications of Dimethoate;

- DFR data for key Canadian crops conducted under typical Canadian use conditions;
- passive dosimetry or biological monitoring data.

To achieve the target MOEs for postapplication workers in agricultural scenarios, new REIs need to be implemented. Appendix IV, Table 2 summarizes the calculated REIs, which need to be added to the appropriate end use product labels. Since the postapplication exposure assessment is based on the maximum number of applications and minimum interval between applications, these also need to be specified on the label.

The proposed REIs are considered agronomically feasible for most uses; however, some of these REIs may not be practical for growers. For high-exposure activities (seed cone harvesting, thinning, pruning, etc.) of Douglas fir seed trees, Sitka spruce and spruce (woodland), calculated REIs ranged from 27 to 105 days and are generally not considered to be agronomically feasible.

3.2.3 Non-Occupational Exposure and Risk Assessment

Non-occupational risk assessment involves estimating risks to the general population, including children, during or after pesticide application. Potential risk to homeowners while using Dimethoate or from contact with commercially treated plants were mitigated through the voluntary discontinuation of domestic class products and residential uses in 2004. Dimethoate can no longer be used in and around homes or other residential areas such as parks, school grounds and playing fields.

3.3 Dietary Risk Assessment

In a dietary exposure assessment, the PMRA determines how much pesticide residue, including residues in milk and meat, may be ingested with the daily diet. Exposure to Dimethoate from potentially treated imports are also included in the assessment. These dietary assessments are age specific and incorporate the different eating habits of the population at various stages of life. For example, the assessments take into account differences in children's eating patterns, such as food preferences and the greater consumption of food relative to their body weight when compared to adults. Dietary risk is then determined by the combination of the exposure and the toxicity assessments. High toxicity may not indicate high risk if the exposure is low. Similarly, there may be risk from a pesticide with low toxicity if the exposure is high.

The PMRA considers limiting use of a pesticide when risk exceeds 100% of the reference dose. PMRA's Science Policy Notice SPN2003-03, *Assessing Exposure from Pesticides, A User's Guide* (http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/spn2003-03/index-eng.php), presents detailed acute and chronic risk assessments procedures.

Surveillance data representative of the national food supply were used to derive a more accurate estimate of residues that may remain on food when it is purchased. These include the Canadian Food Inspection Agency s National Chemical Residue Monitoring Program and the United States Department of Agriculture Pesticide Data Program (PDP). When monitoring data were not available, residue estimates were conservatively based on MRLs or field trial data representing the residues that may remain on food after treatment at the maximum label rate. Specific and empirical processing factors (DEEM - Dietary Exposure Evaluation Model - defaults) and percent crop treated information were also incorporated in the dietary assessment.

Acute and chronic assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 2.03), which uses food consumption data from the United States Department of Agricultures Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998.

For more information on dietary risk estimates or residue chemistry information used in the dietary assessment, see Appendix VIII and IX.

3.3.1 Determination of Acute Reference Dose

To estimate acute dietary risk, the $BMDL_{10}$ of 1.3 mg/kg bw for PND 11 female pups from the comparative cholinesterase study was selected. The endpoint of concern (brain cholinesterase inhibition) was seen after a single oral dose and thus is appropriate for the general population and duration of concern. The database for addressing toxicity to children is considered complete (see *Pest Control Products Act* Hazard Consideration Section) and the endpoint selected (BChE inhibition) is the most sensitive effect to be observed in the young. The *Pest Control Products Act* factor is therefore reduced to 1-fold. An uncertainty factor of 100 was applied to account for interspecies extrapolation (10-fold) and intraspecies variability (10-fold).

ARfD = 0.013 mg/kg bw (1.3 mg/kg bw ÷ 100)

This reference dose is considered protective of the critical endpoint of offspring mortality. Since no data is available that examines the relationship between acute exposure and pup mortality, the cross-fostering study with its short duration of dosing (pre- or post-natal regimes) is considered a conservative surrogate. The ARfD provides a margin of 460 to the dose level showing a clear effect on pup mortality (6 mg/kg bw/day) and a MOS (Margin of Safety) of 230 to the dose level with equivocal effects on mortality (3 mg/kg bw/day); maternal cholinesterase activity would be significantly affected at these levels.

For Omethoate residues, a toxicity adjustment factor of 12 is applied to this exposure scenario to account for the increased toxicity of the metabolite following an acute exposure.

3.3.2 Acute Dietary (Food Alone) Exposure and Risk Assessment

Acute dietary exposure was calculated considering the highest ingestion of Dimethoate and its metabolite Omethoate that would be likely on any one day, and using food consumption and food residue values. A statistical analysis allows all possible combinations of consumption and residue levels to be combined to estimate a distribution of the amount of Dimethoate that might be consumed in a day. When the expected intake of residues is less than the ARfD, then acute dietary risk is considered to be acceptable.

Probabilistic acute dietary exposure analyses were performed to determine the exposure and risk estimates resulting from the use of Dimethoate on domestic and imported agricultural commodities.

The acute dietary exposure estimates at the 99.9th percentile accounted for 37% of the ARfD for the general population and 67% of the ARfD for the most vulnerable population of children (1-2 years old) and is, therefore, not of concern.

3.3.3 Determination of Acceptable Daily Intake

To estimate chronic dietary risk, a $BMDL_{10}$ of 0.2 mg/kg bw/day was selected based on similar values obtained from several repeat-dose oral studies (i.e. 8-day exposures to adult male rats in the comparative cholinesterase gavage study, ~15 day exposures to pregnant dams in the range-finding gavage study, 2-year exposures in the chronic dietary study and in the > 3-month exposures in the multi-generation reproduction dietary study. The endpoint of concern (brain cholinesterase inhibition) was seen after repeated oral doses of varying durations in both dietary and gavage studies and thus is appropriate for the general population and duration of concern. The database for addressing toxicity to children is considered complete (see *Pest Control Products Act* hazard consideration section) and the endpoint chosen is based upon the most sensitive endpoint observed in the young. The *Pest Control Products Act* factor is therefore reduced to 1-fold. An uncertainty factor of 100 was applied to account for interspecies extrapolation (10-fold) and intraspecies variability (10-fold).

ADI = 0.002 mg/kg bw/day ($BMDL_{10}$ of 0.2 mg/kg bw/day ÷ 100)

This reference dose is considered protective of the critical endpoint of offspring mortality. A meta-analysis of pup mortality in the Dimethoate database yielded a $BMDL_5$ of 0.64 mg/kg bw/day. The ADI provides a margin of 320 to the $BMDL_5$. Although no clear association can be made between a specific level of brain cholinesterase inhibition and an increase in pup death, results of the BMD analyses support the conclusion that protection against brain cholinesterase inhibition will also result in protection against pup mortality following repeated dosing.

For Omethoate residues, a toxicity adjustment factor of 3 is applied to this exposure scenario to account for increased toxicity of the metabolite following repeat exposure.

3.3.4 Chronic Dietary (Food Alone) Exposure and Risk Assessment

The chronic dietary exposure was calculated by using the average consumption of different foods and the average residue values on those foods. This expected intake of residues was then compared to the ADI. When the expected intake of residues is less than the ADI, then chronic dietary risk is acceptable.

Deterministic chronic dietary exposure analyses were performed to determine the exposure and risk estimates resulting from the use of Dimethoate on domestic and imported agricultural commodities.

The chronic potential daily intake accounted for less than 14% of the ADI for all sub-populations and is, therefore, not of concern.

3.4 Exposure From Drinking Water

3.4.1 Concentrations in Drinking Water

Dimethoate and Omethoate residues in potential drinking water sources were estimated using monitoring and modelling data. Uncertainties regarding the use of these data as well as the results of the risk estimates for the aggregate (food and water) scenarios are described thereafter.

Modelling data
Estimated environmental concentrations in surface water were calculated using PRZM/EXAMS models in order to simulate Dimethoate runoff from a treated field into an adjacent water body and the fate of this pesticide within the water body. Level 2 modelling data were determined based on the potato use scenario at the 0.528 kg a.i./ha application rate. These values may be characterized as conservative though not unreasonable estimates of possible Dimethoate concentrations in drinking water.

Monitoring data
Surface water monitoring studies from both the United States and Canada were reviewed and assessed. There are a number of uncertainties associated with the monitoring data which limit its use in an acute exposure assessment. In many cases, the data were not accompanied with use data for Dimethoate (rate applied, timing of application, weather conditions). In the absence of this information, it is difficult to conclude if non-detects were a result of non-transport or inappropriate timing of sampling. In addition, because the data are sparse (in both time and location) and concentrations vary in location and time, the maximum concentration reported is unlikely to be the maximum concentration that would be observed in Canada.

Thus, it is likely Dimethoate was not used in some of the areas monitored and that higher concentrations of Dimethoate may occur in other areas not monitored. The Dimethoate monitoring data likely underestimate potential peak exposure.

Omethoate Formation as a Result of Chlorination in Treatment Plants
PMRA has examined available information with respect to the transformation of Dimethoate to Omethoate during treatment of drinking water supplies. The evidence indicates that the formation of Omethoate occurs as a result of oxidation during the chlorination process in water treatment. It is worth noting that the concern for Omethoate formation is primarily restricted to surface water reservoirs. Public drinking water supplies from groundwater sources are often chlorinated, but they are usually deep wells which are less susceptible to contamination by Dimethoate. Private wells, which tend to be shallow, are more vulnerable to contamination, however, chlorination is seldom used to sanitize private well water.

Based on the available, limited information, the PMRA has assumed 100 percent transformation of Dimethoate to Omethoate, which is consistent with the approach taken by the USEPA. Although there is a study that suggests the conversion of Dimethoate to Omethoate could be less than 100 percent under certain conditions, the study had limitations; moreover, water treatment processes vary from plant to plant, and also in time, and the PMRA must consider this in developing a protective assessment. Therefore, the PMRA concludes that the existing data do not support using a transformation of less than 100 percent. Subsequently, to account for the toxicity of Omethoate, the 12× and 3× toxicological adjustment factors were applied directly to all water residue estimates for the acute and chronic risk assessments, respectively.

3.5 Aggregate Exposure and Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal and inhalation). As all residential uses for Dimethoate have been discontinued, the only aggregate exposure scenarios considered were exposure from food and drinking water and exposure for patrons of "Pick Your Own" farms, which includes both dermal and dietary exposure.

3.5.1 Aggregate Dietary and Drinking Water Exposure and Risk Assessment

Drinking water exposure estimates were based on either water modelling or monitoring data. This was done to provide a range of exposure estimates which represent high and low end exposure scenarios. Estimates based on water modelling data provide high end estimates which considers peak residue concentrations that could potentially occur. Estimates based on monitoring data are more refined but are limited as the data are sparse in location and time. Thus, residues estimates derived from monitoring data may not capture peak residue concentrations and may potentially underestimate acute exposure from drinking water.

When using the drinking water modelling data, the acute aggregate exposure from food and drinking water at the 99.9th percentile were 118% and 408% of the ARfD for the general population and infants, respectively. Under this scenario, the complete daily 50 year period distribution of acute concentrations was considered in the residue file editor of DEEM-FCID. When using monitoring data, the acute aggregate exposure at the 99.9th percentile were 56% and 108% of the ARfD for the general population and infants, respectively. Under this scenario, the 95th percentile of the maximum detected concentration from water monitoring studies was used to determine the residues in drinking water.

For the chronic assessment, residues in drinking water were based on level 2 drinking modelling data. There was no need to estimate exposure using drinking water monitoring data as the exposure estimates based on the more conservative drinking water modelling data were not of concern. When using the drinking water modelling data, the chronic aggregate exposure estimates from food and drinking water were below 34% of the ADI for all population groups and is therefore, not of concern.

3.5.2 Aggregate "Pick Your Own" Exposure and Risk Assessment

"Pick Your Own (PYO)" farms are those that allow the public to harvest their own fruits and vegetables. As PYO fruit and vegetable operations become more and more prevalent, the PMRA recognizes the need for a means of assessing exposure to pesticides during hand-harvesting by members of the public. For the purpose of this risk assessment, PYO facilities are considered commercial farming operations that allow public access for harvesting in large-scale fields or orchards treated with commercially labelled Dimethoate products.

The PYO assessment for Dimethoate focuses on strawberries, pears, and cherries, which are likely candidates for consumption during harvest. In addition, the exposure incurred from harvesting or consuming these crops is considered to be representative of all orchard and berry crops that Dimethoate is applied to based on the current use pattern and dietary assessment (i.e. relatively high application rates, transfer coefficients, chronic and acute dietary exposure).

As there is potential for a person to be exposed through contact with treated foliage as well as eating the fruits that they are harvesting, both dermal and dietary risk were aggregated in the PYO risk assessment. Dermal risk was determined by comparing dermal exposure to the short-term dermal toxicological endpoint as described in Section 3.2.2.1. Oral risk was determined by comparing oral exposure to the acute oral NOAEL as described in Section 3.3.1. Given the nature of the PYO exposure scenario, the *Pest Control Products Act* factor was considered. The database for addressing toxicity to children is considered to be complete (see *Pest Control Products Act* hazard considerations section) and the endpoint selected (BChE inhibition) is the most sensitive effect seen in the young. The *Pest Control Products Act* factor is therefore reduced to 1-fold. A target MOE of 100 is required to account for interspecies extrapolation (10-fold) and intraspecies variability (10-fold).

Since members of the public who harvest at PYO facilities may be of any age, the risk assessment was conducted for toddlers, youths and adults. Two exposure pathways were considered: the ingestion of fruit and the dermal exposure incurred through contact of the fruit while harvesting. Maximum residue limits (MRLs) were used to estimate the residue of fruits consumed. MRLs are generally based on the highest residue found in field trials, as could potentially occur in a PYO scenario. Dislodgeable foliar residue data was used to estimate the residue dislodged for dermal exposure during harvesting. Acute consumption of strawberries and cherries was based on the United States Department of Agricultures CSFII dietary survey.

PYO risk assessment for Dimethoate aggregated the dermal risk from hand harvesting fruit and oral risk from consumption of fresh fruit during harvest and chronic dietary exposure (to account for background exposure to Dimethoate from normal diet, including food and drinking water). The risk estimates considered exposure from both Dimethoate and Omethoate residues. A TAF of 12× was applied to Omethoate residues in the acute oral and dermal exposure estimates, while a 3× TAF was applied to Omethoate residues for the background dietary exposure estimates, which were derived from the aggregate chronic dietary and drinking water exposure and risk assessment.

Results of the aggregate PYO risk assessment are presented in Table 1 of Appendix VII.

Calculated combined MOEs for aggregate PYO exposure exceeded the target MOE for all sub-populations and are not of concern.

3.6 Incident Reports

Starting April 26th, 2007, registrants are required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Incidents are classified into six major categories including effects on humans, effects on domestic animals and packaging failure. Incidents are further classified by severity, in the case of humans for instance, from minor effects such as skin rash, headache, etc., to major effects such as reproductive or developmental effects, life-threatening conditions or death.

The PMRA will examine incident reports and, where there are reasonable grounds to suggest that the health and environmental risks of the pesticide are no longer acceptable, appropriate measures will be taken, ranging from minor label changes to discontinuation of the product. Incident reports reflect the observations and opinion of the person reporting it and the Incident Reporting Program does not include validation of the reports. The PMRA collects incident reports in an effort to establish trends and the publishing of individual reports should not be considered as a statement of causality.

As of June 18th, 2009, there have been two human incident reports for Dimethoate in which an exposed individual reported nausea and headache following exposure to a treated area or spillage of an end-use product containing Dimethoate. Nausea and headache are effects consistent with overexposure to organophosphates. One additional incident report detailing packaging failure of an end-use product during transport has been received. An additional report indicated that ocular/nasal discharge, weight loss and death occurred in domestic animals (goats, cats) following aerial treatment of a region of the United States with Dimethoate.

In the USEPA Interim Re-evaluation Document (2007), the agency indicated that Dimethoate had the highest reported incidence of poisonings (non life-threatening) among organophosphate pesticides in residential settings. Residential uses of Dimethoate are no longer registered in Canada or the United States. For the review of the pesticide poisoning incident data for Dimethoate, the USEPA consulted the following databases: (1) OPP Incident Data System (IDS); (2) Poison Control Centres (PCC); (3) California Department of Pesticide Regulation; and (4) National Pesticide Telecommunications Network (NPTN).

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Based on its physical-chemical properties (Section 2.2), Dimethoate is very soluble in water, is not likely to volatilize from moist soil or water surfaces under field conditions, and is not likely to bioaccumulate (K_{ow} = 0.33) in organisms. Environmental fate data for Dimethoate are summarized in Table 1 of Appendix XI. Dimethoate hydrolyses moderately under acidic and neutral conditions, but easily hydrolyses under basic conditions. Phototransformation is not an important route of transformation for Dimethoate in water and soil. The major transformation products of Dimethoate are dimethylthiophosphoric acid and desmethylDimethoate.

Laboratory soil column leaching studies indicate that Dimethoate is very mobile in soil. Dimethoate met all criteria identifying it as leacher. In contrast, field studies conducted in the United States detected Dimethoate and its transformation products in only the top 30 cm deep soil layer. Most probably leaching is offset by microbial degradation. Canadian water monitoring data have shown detections in surface water but not in groundwater.

Dimethoate can enter the aquatic environment through spray drift and runoff from the application field. Based on modelling results and monitoring data, Dimethoate can impact the aquatic environment (Appendix XI). In the total aquatic system Dimethoate is classified as non-persistent to slightly persistent depending on the system and conditions present. Once in the aquatic environment Dimethoate is not expected to persist based on the environmental fate data.

4.2 Effects on Non-target Species

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e. protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC = 1). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Effects on Terrestrial Organisms

A risk assessment of Dimethoate to terrestrial organisms was based upon an evaluation of toxicity data for the following (Table 2, Appendix XI):

- one earthworm species, one bee species and two other invertebrates (acute exposure)
- seven bird and two mammal species representing vertebrates (acute, dietary, reproduction exposure)

A summary of terrestrial toxicity data for Dimethoate is presented in Table 2 (Appendix XI). For the assessment of risk, toxicity endpoints chosen from the most sensitive species were used as surrogates for the wide range of species that can be potentially exposed following treatment with Dimethoate.

Because exposure is dependent on the body weight of the organisms and the amount and type of food consumed, the screening level risk assessment for birds and mammals considers a set of generic body weights (20, 100, 1000 g for birds and 15, 35, 1000 g for mammals) and food preferences (100% small insects for insectivores, 100% fruits for frugivores, 100% grain and seeds for granivores and 100% leaves and leafy crop for herbivores; food items considered at the screening level provide the most conservative EEC for each food guild).

The current label recommends multiple applications with the single application rate ranging from 205 to 12 000 and from 205 to 720 g a.i./ha for ground and aerial applications, respectively. For multiple applications the cumulative rates were calculated taking under consideration the dissipation half-life of Dimethoate in the terrestrial environment (soil, foliage). The screening level risk assessment indicated that exposure to Dimethoate poses a risk to terrestrial invertebrates, mammals and birds. Tables 3 and 4 (Appendix XI) summarize the screening level of risk to terrestrial organisms from Dimethoate. As the level of concern (LOC) was exceeded, the refined risk assessment was conducted. Table 6 (Appendix XI) summarizes the refined risk assessment for terrestrial vertebrates from Dimethoate spray drift and shows that there is still risk but substantially reduced for the most susceptible organisms (for example, RQ reduction of ~70% for the lowest application rate).

4.2.2 Effects on Aquatic Organisms

A risk assessment of Dimethoate to freshwater aquatic organisms was based upon an evaluation of toxicity data for the following (Table 2, Appendix XI):

- four invertebrate species (acute and chronic exposure)
- three fish species (acute and chronic exposure)
- amphibian species using fish as surrogate

Dimethoate is toxic to aquatic invertebrates and fish on an acute basis. Chronic effects to aquatic organisms are also expected. A summary of aquatic toxicity data for Dimethoate is presented in Table 2 (Appendix XI). For the assessment of risk, toxicity endpoints chosen from the most sensitive species were used as surrogates for the wide range of species that can be potentially exposed following treatment with Dimethoate.

The current label recommends multiple applications with the single application rate ranging from 205 to 12 000 and from 205 to 720 g a.i./ha for ground and aerial applications, respectively. For multiple applications the cumulative rates were calculated taking under consideration the dissipation half-life of Dimethoate in the aquatic environment. The screening level risk assessment indicated that Dimethoate pose a risk to freshwater invertebrates, fish and amphibians (based on surrogate data from fish studies) and marine invertebrates and fish. Table 5 (Appendix XI) summarize the risk assessment from Dimethoate to aquatic organisms. As the level of concern (LOC) was exceeded, the refined risk assessment was conducted. Tables 7 and 8 (Appendix XI) summarize the refined risk assessment to aquatic organisms from Dimethoate spray drift and runoff, respectively, and show that there is still risk but substantially reduced for the most susceptible organisms (for example, RQ reduction of ~75% for the highest application rate).

5.0 Value

5.1 Commercial Class Products

Appendix I list all Dimethoate products registered in Canada as of May 2008. Appendix II lists the entire Commercial Class product uses for which Dimethoate is presently registered and shows which uses the registrant does and does not continue to support. Also presented in Appendix II is whether the use was added through the PMRA Minor Use Program. While currently supported by the registrant, the data supporting the minor uses were originally generated by user groups.

Uses of Dimethoate belong to the use site categories of feed crops, food crops, industrial oil seed and fibre crops, forestry sites and ornamental crops. Other supported sites include, in and around farm buildings, such as calf barns, dairy barns, hog pens, poultry houses and other associated buildings, animal quarters (empty), food processing plants (outdoor use), garbage cans (outdoor use), loading docks (outdoor use), warehouses (outdoor), outdoor refuse areas, pastures and wasteland.

5.1.1 Commercial Class Uses for Which Information on the Value of Dimethoate is Sought

Appendix III lists those uses of Dimethoate that the registrant continues to support but that have risk concerns as a result of this re-evaluation.

The PMRA welcomes feedback on the availability and extent of use of chemical alternatives to Dimethoate for the uses listed in Appendix III and information regarding the availability, effectiveness and extent of use of non-chemical pest management practices for any of the registered uses of Dimethoate. This information will allow the PMRA to refine sustainable pest management options for the listed site-pest combinations.

5.2 Domestic Class Products

All registered Domestic Class products of Dimethoate in Canada have been voluntarily discontinued.

5.3 Value of Dimethoate

5.3.1 Agricultural Uses of Dimethoate:

In Canada, dimethoate is registered for use on a wide variety of agricultural sites such as: feed, food, industrial oil seed and fibre, forestry and ornamental crops to control a wide range of insects and mites which includes aphids, beetles, weevils, grasshoppers, flies, leafhoppers, tarnished plant bug, pear psylla, scale insects, thrips, moths, leaf miners, fruit flies and spider mites. These agricultural sites are listed in Appendix II.

Dimethoate is the only organophosphate insecticide registered for the control of aphids on soybean in Canada (AAFC, 2006). It is also registered on soybean to control spider mites for which there are presently no other economical and effective chemical control methods available on this crop (AAFC, 2006; OMAFRA, 2005).

Dimethoate is an important active ingredient in modern crop production. When used in rotation with insecticidal active ingredients from other MoA (Mode of Action) groups, dimethoate plays an important role in delaying development of resistance in insects and mites.

5.3.2 Non-Agricultural Uses of Dimethoate

Dimethoate remains a key insecticide for sustainable pest management on several important non-agricultural sites (Appendix II). Based on Canadian pesticide labels, dimethoate is the only insecticide currently registered in Canada to control insects of Douglas fir (seed trees), Sitka spruce and spruce (woodland use). Dimethoate is effective in reducing infestation levels of the cone gall midge and the seed chalcid (Environment Canada, 1990). Furthermore, its systemic properties make it especially valuable to this use. Table 1 lists the insects registered on these crops.

Table 1 Summary of the insect pests of Douglas fir (seed tree), Sitka spruce and spruce (woodland use) for control of which dimethoate is registered.

Site	Pest(s)
Douglas fir (seed tree)	cone or gall midges, cone moths, seed chalcids, scale midges
Sitka Spruce	Sitka spruce weevil
Spruce (woodland use)	seed and cone insects

[1] based on registered pesticide labels.

The housefly is an important pest of both humans and animals and is also a vector of both human and animal diseases. Dimethoate is effective as a residual spray (Environment Canada, 1990) for up to 6 weeks to control flies in dairy barns, hog pens, poultry houses, vacant animal quarters, farm buildings, food processing plants (outdoors), garbage cans (outdoors), loading docks (outdoors), warehouses (outdoors), outdoor refuse areas, pastures and wasteland. For localized fly control, dimethoate is used around windows, doorways, counters and other areas frequented by flies.

Dimethoate is a valuable alternative to pyrethroids for control of the housefly. Selection pressure from frequent treatments, particularly with a single active ingredient, has led to insecticide resistance in housefly populations in some parts of the world. For example, the housefly has been shown to be resistant to pyrethroids (MoA group 3 insecticides) (Kaufman et al., 2009). Table 2 summarizes the registered alternative active ingredients to dimethoate for control of the housefly on different sites.

Regarding limitations of MoA group 3 insecticides, environmental conditions (mainly temperature) significantly affect the toxicity and efficacy of these insecticides. The toxicity of pyrethroid insecticides is negatively correlated with increasing temperature (Boina et al., 2009) thus pyrethroids are less effective in hot weather (Carter, 2007). For some species of insects, if regular daytime maximum temperatures are well above 25°C, pyrethroids will be efficacious for only a few days at best regardless of the temperature at application (Carter, 2007). In contrast, the toxicity of most organophosphates is considered to be positively correlated with increasing temperature.

Table 2 **Summary of registered alternative active ingredients to dimethoate for control of the housefly.**

Sites	Registered alternatives to dimethoate - Resistance Mode of Action (MoA) group[(1)]	Comments
garbage cans (outdoor)	(1B) Dichlorvos, malathion (3) Pyrethrins Silicon dioxide	**Dichlorvos:** Dichlorvos is currently under re-evaluation. As published in *REV2008-04 Dichlorvos Interim Measures,* application of dichlorvos in outdoor areas and structural sites such as livestock barns, food processing plants, industrial plants, warehouses is still included on the registered labels as of December 20, 2010. **Malathion:** According to *PRVD2010-18*, sites such as manure piles, garbage areas and around buildings, are proposed for phase out. **MoA group 3 limitations:** Regarding the effect of post treatment temperature on toxicity, most of the pyrethroids exhibit a negative correlation to increasing temperature, therefore pyrethroids are less effective in hot conditions. However, organophosphates show a positive correlation to increasing temperature. Most pyrethroids are under re-evaluation.

Sites	Registered alternatives to dimethoate - Resistance Mode of Action (MoA) group[1]	Comments
animal quarters	(1A) Methomyl (1B) Chlorpyrifos, malathion, naled, dichlorvos, tetrachlorvinphos, azamethiphos (3) Pyrethrins, permethrin, cyfluthrin, d-trans allethrin, lambda-cyhalothrin, (4) Thiamethoxam	**Methomyl:** As of December 15, 2010, methomyl is registered for use in hog houses or hog pens. Re-evaluation Note *REV2010-08* provides interim label measures. **Chlorpyrifos:** As of December 2, 2010, chlorpyrifos is registered for use in farm and livestock buildings (indoors and outdoors) for the control of flies and certain other insect pests. **Malathion:** Application of malathion for fly control is still included on the registered labels as of December 20, 2010. **Naled:** As per *RRD2006-24*, the naled re-evaluation has been completed. Naled is registered for use in hog pens as of December 2, 2010. **Tetrachlorvinphos**: Currently under re-evaluation. **Thiamethoxam:** As of December 2, 2010, thiamethoxam is registered for use in poultry houses. See above comments for other alternatives.
food processing plants (outdoor)	(1A) Propoxur (1B) Malathion (3) Permethrin, d-trans allethrin, lambda-cyhalothrin Silicon dioxide	**Propoxur:** Currently under re-evaluation. **Malathion**: According to *PRVD2010-18*, food processing plants are proposed for phase out. See above comments for other alternatives.

Sites	Registered alternatives to dimethoate - Resistance Mode of Action (MoA) group[1]	Comments
warehouses (outdoor)	(1A) Propoxur (3) Permethrin, d-trans allethrin, lambda-cyhalothrin Silicon dioxide	See above comments.
loading docks (outdoor)	(1A) Propoxur (1B) Dichlorvos (3) Permethrin, lambda-cyhalothrin Silcon dioxide	See above comments.
dairy barns	(1A) Methomyl (1B) Chlorpyrifos, malathion, naled, dichlorvos, tetrachlorvinphos, azamethiphos (3) Pyrethrins, permethrin, cyfluthrin, d-trans allethrin, lambda-cyhalothrin (4) Thiamethoxam	See above comments.
hog pens	(1A) Methomyl (1B) Chlorpyrifos, malathion, naled, dichlorvos, azamethiphos, tetrachlorvinphos (3) Pyrethrins, permethrin, d-trans allethrin, lambda-cyhalothrin, cyfluthrin (4A) Thiamethoxam	See above comments.

Sites	Registered alternatives to dimethoate - Resistance Mode of Action (MoA) group(1)	Comments
poultry houses	(1A) Methomyl (1B) Chlorpyrifos, malathion, naled, dichlorvos, azamethiphos, tetrachlorvinphos (3) Pyrethrins, permethrin, cyfluthrin, d-trans allethrin, lambda-cyhalothrin, (4A) Thiamethoxam Beauveria bassiana strain HF23 Silicon dioxide	**Malathion:** According to *PRVD2010-18*, poultry houses are proposed for phase out. See above comments for other alternatives.
farm buildings	(1A) Methomyl (1B) Chlorpyrifos, dichlorvos, azamethiphos, malathion, naled, tetrachlorvinphos (3) Pyrethrins, permethrin, d-trans allethrin, lambda-cyhalothrin, cyfluthrin (4) Thiamethoxam	**Malathion:** According to *PRVD2010-18*, farm buildings (indoor) are proposed for phase out. See above comments for other alternatives.

[1] based on pesticides registered in Canada and PMRA Insecticide Resistance Mode of Action (MoA) Directive - DIR99-06

6.0 Toxic Substances Management Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's *Toxic Substances Management Policy*, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

During the review process, Dimethoate was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with the use of Dimethoate were also considered, including major transformation products formed in the environment, and contaminants and formulants in the technical product and in the end-use products. Dimethoate and its transformation products were evaluated against the following Track 1 criteria: persistence in soil ≥182 days; persistence in water ≥182 days; persistence in sediment ≥365 days; persistence in air ≥2 days; bioaccumulation log $K_{ow} \geq 5$ or BCF ≥5000 (or BAF ≥5000). In order for Dimethoate or its transformation products to meet Track 1 criteria, the criteria for both bioaccumulation and persistence (in one media) must be met. The technical product and end-use products, including formulants, were assessed against the contaminants identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern, Part 3 Contaminants of Health or Environmental Concern.* The PMRA has reached the following conclusions:

- Dimethoate does not meet Track 1 criteria. The log octanol-water partition coefficient (log K_{ow}) of Dimethoate is 0.02, which is below the TSMP Track 1 cut-off criterion for log K_{ow} 5.0. Dimethoate does not meet the Track 1 criterion for persistence, as its half-life values in water (13-17 days) and soil (2-4 days) are below the Track 1 criteria. Dimethoate does not meet the Track 1 criterion for persistence in air because volatilisation is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on its vapour pressure (8.25×10^{-6}mm Hg) and Henry's law constant (9.95×10^{-11} atm m^3/mole). Dimethoate does not meet the Track 1 criterion for bioaccumulation, as its log K_{ow} (0.33) is below the Track 1 criterion. Therefore, Dimethoate does not meet the Track 1 criteria, and is not considered a Track 1 substance.

- Dimethoate does not form any transformation products that meet the Track 1 criteria.

- There are no Track 1 contaminants in the technical product.

- Therefore, the use of Dimethoate is not expected to result in the entry of Track 1 substances into the environment.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, formulants and contaminants in the technical and end-use products are assessed against the formulants and contaminants identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*. This list of formulants and contaminants of health and environmental concern are identified using existing policies and regulations including: the federal Toxic Substances Management Policy; the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol); and the PMRA Formulants Policy as described in the PMRA Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document*. The *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* is maintained and used as described in the PMRA Notice of Intent NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act*.

The *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* consists of three parts:

- Part 1: Formulants of Health or Environmental Concern;
- Part 2: Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions; and
- Part 3: Contaminants of Health or Environmental Concern.

The contaminants to which Part 3 applies meet the federal Toxic Substances Management Policy criteria as Track 1 substances, and are considered in section 6.1. The following assessment refers to the formulants and contaminants in Part 1 and Part 2 of the list.

Technical grade Dimethoate and the end-use products do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for Dimethoate is adequate to define the toxic effects that may result from exposure to Dimethoate. Dimethoate was not found to be genotoxic or teratogenic in animal studies. Dimethoate is unlikely to pose a carcinogenic risk to humans.

Following administration to pregnant and young rats, an increase in mortality has been observed at dose levels above those which inhibit cholinesterase activity.

The target for Dimethoate is the nervous system, including effects on neurobehavioural parameters and acetylcholinesterase inhibition. For animals exposed to Dimethoate, brain cholinesterase is the most sensitive compartment for effects on cholinesterase, with inhibition being observed in a variety of species and by all routes of exposure. Young animals were determined to be of similar sensitivity to cholinesterase inhibition when compared to adults. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

7.1.1 Occupational Risk

Risk estimates associated with mixing, loading and application of Dimethoate to Douglas fir seed trees, Sitka spruce, spruce (woodland), structural sites, paint-on-treatments, right-of-way application and soil drench application (carnations) do not reach the target MOE, even when engineering controls and personal protective equipment are used. As such, it is proposed that registration of Dimethoate for these uses be discontinued. In addition, postapplication risks for workers are of concern for Douglas fir, Sitka spruce and spruce (woodland) and mitigation measures that would diminish the risk are not considered agronomically feasible.

The risk estimates associated with mixing, loading, and application of all other Dimethoate uses are not of concern provided that engineering controls, personal protective equipment, and additional mitigation measures as listed in Section 8 are implemented. Postapplication risks for workers are not of concern when the proposed mitigation measures (REIs) are applied. Some of the proposed REIs may not be considered agronomically feasible and the PMRA is requesting feedback on this aspect prior to finalizing the decision.

7.1.2 Dietary Risk from Food

Acute and chronic dietary risk assessments demonstrated that there were no dietary concerns for any population subgroups, including infants, children, teenagers, adults and seniors.

7.1.3 Non-Occupational Risk

There are no domestic products or residential uses of Dimethoate, therefore, a residential risk assessment is not required.

7.1.4 Aggregate Risk

Aggregate Dietary and Drinking Water Risk
Exposure and risk from drinking water was assessed using both modelling and monitoring drinking water data. The acute aggregate risk assessment based on of drinking water modelling data resulted in risk estimates that were of concern for most population subgroups including the general population and infants. The use of limited drinking water monitoring indicates an acceptable acute risk for all population groups, except infants where the estimated exposure from food and drinking water accounted for 108% of the ARfD.

The chronic dietary risk assessment based on drinking water modelling data demonstrated that there were no dietary concerns from exposure to drinking water and food for any of the population subgroups. There was no need to estimate exposure and risk using drinking water monitoring data as the exposure estimates based on the more conservative drinking water modelling data were not of concern.

In light of the conservative assumptions made regarding 100% conversion of Dimethoate to Omethoate during water chlorination, the PMRA concludes that there is a high level of uncertainty in the current aggregate dietary and drinking water exposure and risk assessment. Additional data is required to determine the degree of Dimethoate transformation to Omethoate during water chlorination under various water quality regimes. A revised aggregate dietary and drinking water assessment will be conducted once the required water treatment assay is received.

Aggregate "Pick Your Own" Risk
Aggregate risk estimates for exposure of patrons at 'Pick Your Own' facilities are not of concern for orchard and berry crops.

7.2 Environmental Risk

The risk assessment of Dimethoate indicates adverse effects on non-target terrestrial invertebrates and vertebrates and aquatic organisms. There is a potential that Dimethoate may appear in surface water through runoff. To reduce the effects of Dimethoate in the environment, mitigation in the form of precautionary label statements and buffer zones are required.

7.3 Value

Dimethoate is one of the insecticides subject to re-evaluation in Canada. It is registered in Canada for a wide range of uses on both agricultural and non-agricultural sites to control various chewing and sucking insects.

Dimethoate is proposed for removal from Canadian labels for the control of insect pests of Douglas fir (seed trees), Sitka spruce, and spruce (woodland use). Furthermore, dimethoate is the only insecticide currently registered in Canada on these sites.

It is also proposed that structural uses of dimethoate be removed from Canadian labels. Dimethoate is effective as a residual spray for housefly control on many structural sites. It controls the housefly for up to 6 weeks following application and is effective in hot weather.

Dimethoate is important in the resistance management of insect pests as it provides an option for rotation with insecticides from other chemical groups. In addition, for some of the uses for which it is registered, there are few if any other effective registered alternatives.

For further details, all dimethoate products registered in Canada as of May 2008 are listed in Appendix I. Appendix II lists all of the currently registered Commercial Class uses.

8.0 Proposed Regulatory Decision

8.1 Proposed Regulatory Actions

8.1.1 Proposed Regulatory Action Related to Human Health

8.1.1.1 Toxicological Information

Dimethoate is of high oral and low dermal and inhalation toxicity. Dimethoate exhibits moderate eye and minimal dermal irritation in rabbits and is not a dermal sensitizer in guinea pigs under test conditions. Consequently, the following hazard statement should appear on the label of the technical product:

> POISON, DANGER. WARNING: EYE IRRITANT.

The labels of pesticide products carry statements regarding the symptoms of poisoning and treatment, which are especially important for those who maybe overexposed when working with the product in a commercial or industrial setting. Based on additional studies included in the toxicology assessment, the label text of the products containing dimethoate should also be expanded and/or standardized (see Appendix IV).

8.1.1.2 Proposed Mitigation for Mixer, Loader, and Applicator Exposure and Postapplication Exposure

Unsupported Uses:
The technical registrant, Cheminova Inc., no longer supports residential uses and therefore these uses were not assessed for re-evaluation. As all residential uses of Dimethoate have been discontinued and phased out, all references to outdoor residential uses, including use around homes and recreation areas, must be removed from the labels. In addition, the following statement should appear on all Dimethoate labels:

> "This product is not to be used around homes or other residential areas such as parks, school grounds and/or playing fields. It is not for use by homeowners or other uncertified users."

Uses Identified as Risks of Concern:
Health risk mitigation measures were considered for this assessment. Despite these measures, MOEs for mixer/loaders and applicators for some scenarios are below the target MOE. Thus, due to the risk concerns identified, it is proposed that all the label directions concerning the following uses and application equipment be amended as follows:

- All label directions concerning the application of Dimethoate to Douglas fir seed trees, Sitka spruce, and spruce (woodland use) are proposed for removal;
- All label directions concerning application to structural sites are proposed for removal;
- All label directions concerning paint-on treatments are proposed for removal;
- Labels should clearly state not to use right-of-way sprayer application equipment;
- Label directions for soil drench application to carnations are proposed for removal.

Number of Applications:
The available dislodgeable foliar residue data support two applications with a treatment interval of seven or ten days. Therefore, it is necessary to amend the conditions of registration for some crops accordingly (see Appendix IV).

Maximum Spray Volume:
For the purpose of the risk assessment, the maximum water volume of spray solution was assumed to be 1000 L/ha, or 3000 L/ha for fruit trees (pears, peaches, and cherries), unless otherwise stated on the label. Therefore, labels should state do not exceed a maximum spray volume of 3000 L/ha for fruit trees and do not exceed a maximum spray volume of 1000 L/ha for all other crops unless otherwise stated on the current label. Where maximum spray volume for fruit trees (pears, peaches, cherries) is not specified the following statement should be added to labels:

> "Apply at the recommended rate; do not exceed a maximum spray volume of 3000 L per hectare unless otherwise stated."

And the following statement should be added to all other labels:

> "Apply at the recommended rate; do not exceed a maximum spray volume of 1000 L per hectare unless otherwise stated."

Use Precautions:
There may be potential for bystander exposure to drift following pesticide application to agricultural areas. In the interest of promoting best management practices and to minimize human exposure from spray drift or from spray residues resulting from drift, the following label statement is required:

> "Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings."

Incidental exposure to dimethoate is a possibility which necessitates the following label statement for all products:

> "Keep the following personal protective equipment immediately available for use in case of emergency (i.e. a broken package, spill, or equipment breakdown): chemical-resistant coveralls, chemical-resistant gloves, chemical-resistant head gear and a respirator."

For clarification, it is recommended that the following statements should be added to all dimethoate product labels:

> "Not for use in greenhouses."

Engineering Controls and Personal Protective Equipment
Label statements are proposed to include appropriate engineering controls and personal protective equipment for various use scenarios in order to mitigate the risk of worker exposure to Dimethoate (see Appendix IV) .

Restricted-entry Intervals:
Based on the postapplication risk to workers, new REIs have been proposed (see Appendix IV).

8.1.1.3 Residue Definition for Risk Assessment and Enforcement

The current residue definition for risk assessment and enforcement is Dimethoate and Omethoate. Based on animal and plant metabolism data available, the proposed residue definition should remain as Dimethoate (O,O-dimethylS-[2-(methylamino)-2-oxoethyl] phosphorodithioate) and Omethoate (O,O-dimethyl S-[2-(methylamino)-2-oxoethyl] phosphorothioate).

8.1.1.4 Maximum Residue Limits for Dimethoate in Food

In general, when the re-evaluation of a pesticide has been completed, the PMRA intends to update Canadian maximum residue limits (MLRs) and to remove MRLs that are no longer supported. The PMRA recognizes, however, that interested parties may want to retain an MRL in the absence of a Canadian registration to allow legal importation of treated commodities into Canada. The PMRA requires similar chemistry and toxicology data for such import MRLs as those required to support Canadian food use registrations. In addition, the Agency requires residue data that are representative of use conditions in exporting countries, in the same manner that representative residue data are required to support domestic use of the pesticide. These requirements are necessary so that the PMRA may determine whether the requested MRLs are needed and to ensure they would not result in unacceptable health risks.

After the revocation of an MRL or where no specific MRL for a pest control product has been established in the *Pest Control Products Act*, subsection B.15.002(1) of the *Food and Drugs Act* applies. This requires that residues do not exceed 0.1 ppm and has been considered a general MRL for enforcement purposes. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document *DIS2006-01 Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*.

As indicated in Table 8.1.1.4, the *Pest Control Products Act* specify MRLs for Dimethoate on a variety of crops. Residues in all other agricultural commodities, including those approved for treatment in Canada but without a specified MRL must not exceed the general MRL of 0.1 ppm.

Revocation of the Canadian MRL for apples, cabbage, and spinach is proposed as Dimethoate use on these commodities have been voluntary discontinued by the registrant in both Canada and the United States. In addition, the MRL for lettuce should be changed to specify to lettuce (leaf) only as use on lettuce (head) has also been discontinued.

Parties interested in supporting a Dimethoate MRL should contact the PMRA during the comment period of this document to discuss the submission of appropriate data. This includes petitionining of import MRLs for commodities such as artichoke, corn, cotton, endives, citrus, guava, lentils, mango, melons (cantaloupe, honeydew, watermelon), mustard greens, olives, pecan, starfruit, sorghum, and sugar beet.

Table 8.1.1.4 Dimethoate MRLs for Commodities Approved for Treatment in Canada

Commodity	MRL (ppm)
Meat, Fat, Milk, Eggs and Meat By-products of Cattle, Goats, Horses, Sheep, Swine, and Poultry	0.1*
Apples	2
Asparagus	0.1*
Barley	0.1*
Beans	1
Beet tops	2
Blueberries	1
Broccoli	2
Broccoli, Chinese	0.1*
Brussel Sprouts	0.1*
Cabbage	2
Cabbage, Chinese (Bok Choi)	0.1*
Canola	0.1*
Cauliflower	2
Celery	1
Cherries	2
Chicory	0.1*
Citrus Fruits	1.5**
Eggplant	0.1*
Flax	0.1*
Filberts or Hazelnuts	0.1*
Kale	2
Lettuce	2
Oats	0.1*
Peaches (non bearing)	0.1*

Commodity	MRL (ppm)
Pears	2
Peas	0.5
Peppers	0.5
Potatoes	0.1*
Rye	0.1*
Safflower	0.1*
Spinach	2
Soybeans (grain)	0.1*
Strawberries	1
Swiss Chard	2
Tomatoes	0.5
Turnip Tops	2
Wheat	0.1*

* By virtue of subsection B.15.002(1) of the Food and Drug Regulations, the maximum residue limit of foods for which MRLs have not specifically been established is 0.1 ppm.

** For import commodities.

8.1.1.5 Proposed Mitigation for Dietary and Drinking Water Exposure

The following mitigation measures are proposed to reduce Dimethoate exposure from food and drinking water. The increase or addition of pre-harvest intervals (PHI) and pre-grazing intervals (PGI) are proposed to ensure that residues do not exceed MRLs in treated crops. Reduction in application rates are proposed to reduce drinking water exposure estimates.

Crop	Proposed Label Revisions for Commercial Products
All Crops/Labels	30 days plant interval for fields treated with Dimethoate
Alfalfa	Minimum 10 days pre-harvest interval (PHI)/pre-grazing interval (PGI)
Asparagus	Dimethoate should be applied post harvest only
Blueberry	Minimum 21 days PHI
Broccoli, Cauliflower	Minimum 7 days PHI
Celery	Minimum 7 days PHI
Cereals (wheat, barley, rye, oats)	Minimum 14 days PGI and 35 days PHI
Kale, Lettuce (leaf), Swiss Chard, Turnip (greens)	Minimum 14 days PHI
Peach (non-bearing)	Minimum 40 days PHI
Peas	Maximum rate reduced to 0.18 kg a.i./ha
Pear	Maximum rate reduced to 1.44 kg a.i./ha Minimum 28 days PHI
Potato, Tomato	Maximum rate reduced to 0.48 kg a.i./ha

8.1.2 Proposed Regulatory Action Related to Environment

The risk assessment has indicated that adverse effects on non-target terrestrial and aquatic organisms are expected. To reduce the effects of Dimethoate in the environment, mitigation in the form of precautionary label statements and buffer zones are required. Environmental mitigation statements are listed in Appendix IV (Label Amendments for Products Containing Dimethoate).

8.2 Additional Data Requirements

8.2.1 Data Requirements Related to Toxicology

Data is required to confirm the Agency's conclusion that the product is acceptable for continued registration and includes:

DACO 4.4.4	Concurrent historical control data for vascular tumors (hemangiomas and hemangiosarcomas) for the Wistar rat in the 2-year chronic toxicity/oncogenicity study.
DACO 4.5.12	Acute Comparative Cholinesterase Study investigating the ability of metabolites of concern to inhibit brain cholinesterase following exposure. Metabolites of concern include: O-desmethyl Omethoate, O-desmethyl Omethoate carboxylic acid, O-desmethyl isoDimethoate and Dimethoate carboxylic acid.

8.2.2 Data Requirements Related to Occupational Exposure Assessment

No Section 12 data requirements are requested at this time. Uses for which there is a risk concern or no data to assess have been proposed for phase out (Douglas fir seed trees, Sitka spruce and spruce (woodland), paint-on applications, right-of-way sprayer equipment, soil drench applications (carnations) and applications to structural sites). Should the registrant wish to support continued registration of these uses, additional data are required.

8.2.3 Data Requirements Related to Food Residue Chemistry

In most cases the available residue data do not fully satisfy the requirements as described in Regulatory Directive DIR98-02, *Residue Chemistry Guidelines*. Therefore, the following data are required under section 12 of the *Pest Control Procucts Act* to support the continued registration of Dimethoate.

DACO 6.2	Livestock metabolism including adequate data depicting nature of the residue in milk matrices and adequate radiovalidation.
DACO 6.3	Plant metabolism.
DACO 7.2.1	Supervised residue trial analytical methodology.
DACO 7.2.2	Enforcement analytical methodology.
DACO 7.2.3	Inter-Laboratory analytical methodology validation.
DACO 7.2.4	Multi-residue analytical methodology evaluation

DACO 7.3	Freezer storage stability in both plant and animal matrices.
DACO 7.4.1	Magnitude of residue data for O-desmethyl Omethoate, O-desmethyl Omethoate carboxylic acid, O-desmethyl IsoDimethoate, and Dimethoate carboxylic acid.
DACO 7.4.3	Confined crop rotation.
DACO 7.4.5	Processing study for safflower.
DACO 7.5	Livestock, poultry, egg and milk residue data (from feeding of treated crops).

Additional data is required to address the uncertainties regarding drinking water exposure estimates. Refer to Section 8.2.4 (Proposed Regulatory Action Related to Environment) for further information.

The following additional confirmatory data are required to support any expansion of Dimethoate use:

DACO 7.4.1	Supervised field trials conducted according to Canadian GAP, within geographic zones specified in the DIR98-02, *Residue Chemistry Guidelines*, and conducted according to contemporary standards for the following crop uses: asparagus, barley, beans, beets, blueberries, broccoli, brussel sprouts, canola, cauliflower, chicory, flax, lettuce, peas, pears, peppers, potatoes, safflower, soybean, strawberry, Swiss chard, tomato, and turnips.

8.2.4 Data Requirements Related to Environmental Risks

DACO 8.5	Non-guideline Study: To address the uncertainties around the formation of the oxygen analog (Omethoate) resulting from chlorination, a laboratory study investigating the effects of different chlorination methods at different pHs is required. These data will allow the PMRA to potentially refine the aggregate dietary and drinking water assessment.

8.2.5 Data Requirements Related to Value

Stakeholders are requested to comment on the value of uses proposed for removal.

List of Abbreviations

µg	micrograms
ADI	acceptable daily intake
a.i.	active ingredient
ARfD	acute reference dose
atm	atmospheres
bw	body weight
CFIA	Canadian Food Inspection Agency
cm	centimetre(s)
d	day(s)
DACO	data code
DEEM$^{\circledR}$	Dietary Exposure Evaluation Model
DER	Data Evaluation Report
DFR	dislodgeable foliar residue
DT_{50}	dissipation time to 50% (the dose required to observe a 50% decline in the test population)
DWLOC	drinking water level of comparison
DNA	deoxyribonucleic acid
EChE	erythrocyte cholinesterase
EEC	expected environmental concentration
EP	end-use product
EXAMS	Exposure Analysis Modeling System
F_0	parental animals
F_1	first filial generation
F_2	second filial generation
g	gram(s)
GAP	good agricultural practice
GC-FPD	Gas Chromatography-Flame Photometric Detector
GC-MSD	Gas Chromatography-Mass Selective detector
GC-NPD	Gas Chromatography-Nitrogen Phosphorous Detector
ha	hectare(s)
HAP	hours after application
Hg	mercury
IPM	integrated pest management
IRED	Interim Reregistration Eligibility Decision (USEPA Document)
K_d	adsorption coefficient
kg	kilogram(s)
K_{oc}	organic carbon partition coefficient
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LC_{50}	lethal concentration to 50% (a concentration causing 50% mortality in the test population
LD_{50}	lethal dose to 50% (a dose causing 50% mortality in the test population)
LEACHM	Leaching Estimation and Chemistry Model
LOAEL	lowest observed adverse effect level
LOD	limit of detection

LOEC	lowest observed effect concentration
m	metre(s)
m^3	metre(s) cubed
mg	milligram(s)
min	minute(s)
mm	millimetre(s)
mm Hg	millimetre mercury
MOE	margin of exposure
MRL	maximum residue limit
nm	nanometre
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
OC	organic carbon
OP	organophosphate
PChE	plasma cholinesterase
PCPA	*Pest Control Product Act*
PDP	Pesticide Data Program (United States data)
PHI	preharvest interval
pH	-log10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
p*K*a	-log10 acid dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppb	parts per billion
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
PRZM	Pesticide Root Zone Model
PSI	pre-slaughter interval
Q_1*	cancer potency factor
RED	Reregistration Eligibility Decision
REI	restricted-entry interval
ROC	residue of concern
RQ	risk quotient
TC	transfer coefficient
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
URMULE	User Requested Minor Use Label Expansion
USEPA	United States Environmental Protection Agency
USDA	United States Department of Agriculture
USFDA	United States Food and Drug Administration

Appendix I Registered dimethoate products as of 30 May, 2008[1]

Registration Number	Marketing Class[2]	Registrant	Product Name	Formulation Type	Guarantee
8277	C+R	Cheminova Canada, Inc	Cygon 480 Systemic Insecticide	SN-Solution	DIM-480 g/L
9382	C+R	United Agri Products Canada Inc	Lagon 480 E Insecticide	EC- Emulsifiable Concentrate or Emulsion	DIM-480 g/L
9807	C	Inter-provincial Cooperative Limited	Cygon 480 EC Systemic Insecticide	EC- Emulsifiable Concentrate or Emulsion	DIM-480 g/L
12864	C	Agrium Advanced Technologies RP Inc	Wilson Dimethoate 480 EC Systemic Insecticide	EC- Emulsifiable Concentrate or Emulsion	DIM-480 g/L
14478	C	Vétoquinol N. –A, Inc.	Di-Thoate 4e	EC- Emulsifiable Concentrate or Emulsion	DIM-480 g/L
25650	C	Cheminova Canada, Inc	Cygon 480-Orn Systemic Insecticide	EC- Emulsifiable Concentrate or Emulsion	DIM-480 g/L
25651	C	Cheminova Canada, Inc	Cygon 480-Ag Systemic Insecticide	EC- Emulsifiable Concentrate or Emulsion	DIM-480 g/L
19068	M	Cheminova Canada, Inc	Chemathoate Manufacturing Concentrate	SN-Solution	DIM-55 %
19067	T	Cheminova Canada, Inc	Chemathoate Technical	SO-Solid	DIM-98.40 %

[1] excluding discontinued products and products with a submission for discontinuation

[2] C= Commercial, M= Manufacturing Concentrate, R= Restricted Class, T = Technical Class

Appendix II Registered Commercial Class uses of Dimethoate in Canada as of May 30, 2008 based on the PMRA's Label Collection.

Site(s)	Pest(s)	Formulation Type[1]	Application Rate[2] a.i.		Max. # of Applications/ Season[3]	Min. Interval Between Applications (days)	Supported Use[4]
			Maximum Single	Maximum Cumulative			
Use-site Category 13: Terrestrial Feed Crops							
Alfalfa	Aphids, leafhoppers, alfalfa weevil larvae, lygus bug	SN	204 g/ha	612 g/ha	**3**	not stated	Y
	Blotch leaf miner, grasshoppers - nymphs		264 g/ha	792 g/ha			
	Grasshoppers - adults	SN, EC	408-432 g/ha	1224-1296 g/ha			
	Aphids, leafhoppers, reduction of alfalfa weevil larvae, lygus bugs	EC	204 g/ha	612 g/ha			
	Grasshoppers - nymphs						
	Blotch leaf miner, grasshoppers - nymphs		264 g/ha	792 g/ha			
Alfalfa (for seed and forage production)	Aphids, leafhoppers, alfalfa weevil larvae	EC	204 g/ha	408 g/ha	2	not stated	Y
	Blotch leaf miner		264 g/ha	264 g/ha	1	n/a	
	Grasshoppers-nymphs						
	Grasshoppers-adults or winged		408-432 g/ha	816-864 g/ha	2	not stated	
	Aphids, leaf hoppers, lygus bugs, plant bugs, alfalfa weevil larvae		204 g/ha	408 g/ha	2		
Alfalfa (seed production)	Lygus bug, plant bugs	SN, EC	528 g/ha	528 g/ha	1	n/a	Y
Canary Grass (seed production)	Aphids	SN, EC	240 g/ha	480 g/ha	2	**30**	Y
Forage crops (grasses, alfalfa, hay, clover)	Grasshoppers-low infestations aphids	EC	204-264 g/ha	408-528 g/ha	2	5	Y
Forage crops (grasses, hay, clover)	Lygus bug, plant bugs, grasshoppers - low infestations	SN	204 g/ha	408 g/ha	2	5	Y
	Grasshoppers - nymphs		264 g/ha	528 g/ha			
	Grasshoppers - adults		408-480 g/ha	816-960 g/ha			

Site(s)	Pest(s)	Formulation Type[1]	Application Rate[2] a.i.		Max. # of Applications/ Season[3]	Min. Interval Between Applications (days)	Supported Use[4]
			Maximum Single	Maximum Cumulative			
Forage crops, grain	Lygus bugs, plant bugs	EC	204 g/ha	408 g/ha	2	5	Y
	Grasshoppers - low infestations		204-264 g/ha	408-528 g/ha			
	Grasshoppers - nymphs		264 g/ha	528 g/ha			
	Grasshoppers - adults		408-480 g/ha	816-960 g/ha			
Sweet Clover	Sweet clover weevil	EC	408-528 g/ha	816-1056 g/ha	2	5	Y
Sweet Clover, Red Clover, Alsike Clover	Sweet clover weevil	SN, EC	408-528 g/ha	816-1056 g/ha	2	5	Y
Use-site Category 14: Terrestrial Food Crops							
Asparagus	Asparagus aphid	SN, EC	1.104 kg/ha	6.624 kg/ha	6	21	Y
Beans	Aphids, bean beetles, leafhoppers, leaf miners, lygus bugs, mites, tarnished plant bug	SN, EC	336-480 g/ha	672-960 g/ha	2	14	Y
Beans (pole, snap)		EC		1008- 1440 g/ha	3		
Beet greens	Aphids, leafhoppers	SN, EC	336 g/ha	672 g/ha	2	3	Y
Beets	Tarnished plant bug	EC	336 g/ha	1008 g/ha	3	7	Y
Blueberry (highbush)	Blueberry maggot	SN, EC	398.4 g/ha	796.8 g/ha	2	10	Y, M
Blueberry (lowbush & highbush)		EC	288-396 g/ha	576 -792 g/ha			
			278.4-396 g/ha	556.8-792 g/ha			
Blueberry (lowbush)		SN, EC	278.4-398.4 g/ha	556.8-796.8 g/ha			
Broccoli, Cauliflower	Aphids	SN, EC	336-480 g/ha	1008-1440 g/ha	3	7	Y
	Thrips		264-600 g/ha	792-1800 g/ha			
Brussel sprouts	Aphids	SN, EC	336-480 g/ha	1008-1440 g/ha	3	7	Y
Celery	Aphids-including carrot, green peach and foxglove aphids	EC	336 g/ha	1008 g/ha	3	7	Y

Site(s)	Pest(s)	Formulation Type[1]	Application Rate[2] a.i.		Max. # of Applications/ Season[3]	Min. Interval Between Applications (days)	Supported Use[4]
			Maximum Single	Maximum Cumulative			
Chicory, Chinese broccoli	Aphids	SN, EC	288-480 g/ha	864-1440 g/ha	3	7	Y
Chinese broccoli, pak choi, chicory							
bok choi							N
Eggplant	Tarnished plant bug	SN, EC	240-336 g/ha	480-672 g/ha	2	7	Y
Filberts, Hazelnuts	Aphids	SN, EC	2.4 kg/ha	2.4 kg/ha	1	n/a	Y
Kale	Aphids, leafhoppers	SN, EC	336 g/ha	672 g/ha	2	15	Y
Lettuce (not head), Swiss chard	Aphids, leafhoppers	SN, EC	336 g/ha	672 g/ha	2	7	Y
Peaches (nonbearing)	Aphids, mites	SN, EC	480-720 g/1000 L; 1.44 - 2.16 kg/ha	2.88 - 4.32 kg/ha	2	7	Y
	Tarnished plant bug		816 g/ha	1632 g/ha			
			240 g/1000 L	1440 g/ha			
			840 g/ha	1680 g/ha			
Pears	Tarnished plant bug	SN, EC	300 g/1000 L; 900 g/ha	1800 g/ha	2	7	Y
	Pear psylla, aphids, mites		480-600 g/1000 L; 1.44 -1.8 kg/ha	2.88-3.6 kg/ha			
Peas	Aphids	EC	132-204 g/ha	528-816 g/ha	4	14	Y
Peas (canning & field)	Aphids	SN, EC	132-204 g/ha	264-408 g/ha	2		
				528 - 816 g/ha	4		
Peppers	Aphids, maggot	SN, EC	336-480 g/ha	1008-1440 g/ha	3	7	Y
	Aphids, pepper maggot						
Potatoes	Aphids, leafhoppers, tarnished plant bug	EC	264-480 g/ha	792-1440 g/ha	3	7	Y
			264 -528 g/ha	792-1584 g/ha			
	Aphids, leafhoppers	SN, EC	264 - 528 g/ha	792-1584 g/ha			
Safflower	Grasshoppers (nymphs, adults)	SN, EC	264-480 g/ha	528-960 g/ha	2	5	Y

Site(s)	Pest(s)	Formulation Type[1]	Application Rate[2] a.i.		Max. # of Applications/ Season[3]	Min. Interval Between Applications (days)	Supported Use[4]
			Maximum Single	Maximum Cumulative			
Sour Cherries	Black and Western cherry fruit fly maggot	SN, EC	1.08 kg/ha	2.16 kg/ha	2	14	Y
Sour Cherries, Sweet Cherries	Cherry fruit fly	EC	240 g/1000 L; 720 g/ha	1440 g/ha	2	14	Y
Strawberries (bearing & non-bearing)	Aphids, mites	EC	480 g/ha	1440 g/ha	3	30	Y
Strawberries (bearing)	Tarnished plant bug	SN	1.32 kg/ha	2.64 kg/ha	2	10	Y
		EC	600 g/ha	1.20 kg/ha			
	Tarnished plant bug, aphids, mites	EC	1.32 kg/ha	2.64 kg/ha			
Strawberries (bearing, non bearing)	Aphids, mites	SN, EC	1.08 kg/ha	2.16 kg/ha	**2**	**10**	Y
		EC				30	
Sweet Cherries	Black and Western cherry fruit fly maggot	SN, EC	1.08 kg/ha	1.08 kg/ha	1	**n/a**	Y
Tomatoes (field)	Aphids, leafhoppers	SN, EC	264-528 g/ha	792-1584 g/ha	3	**6**	Y
	Aphids, leafhoppers, tarnished plant bug	EC	264-480 g/ha	792-1440 g/ha			
Turnip greens	Aphids, leafhoppers	SN, EC	336 g/ha	672 g/ha	2	**3**	Y
Use-site Category 20: Structural							
around homes, recreation areas	houseflies	EC	4.8 g/L	n/a	**2**	not stated	N
garbage cans, animal quarters (empty), food processing plants, warehouses, loading docks, refuse areas	houseflies	EC	12.0 g/L	n/a	**2**	not stated	P
			4.8 g/L				
		EC,SN	9.6-12.0 g/L				

Site(s)	Pest(s)	Formulation Type[1]	Application Rate[2] a.i.		Max. # of Applications/ Season[3]	Min. Interval Between Applications (days)	Supported Use[4]
			Maximum Single	Maximum Cumulative			
dairy barns, hog pens, calf barns, poultry houses & other farm buildings	houseflies	SN, EC	9.6-12.0 g/ L **per 10 m^2**	n/a	2	14	P
		EC	12.0 g/L **per 10 m^2**				
Use-site Category 27: Ornamentals Outdoor							
Arborvitae	Aphids, bagworms, mites	SN, EC	960 g/1000 L; 960 g/ha	2880 g/ha	3	14	Y
Azaleas	Lace bugs, leaf miners, mites, whiteflies	EC	480 g/1000 L; 480 g/ha	1440 g/ha	3	14	Y
Birch	Aphids, leaf miners	SN, EC	240 g/1000 L	480 g/ha	2 (foliar)	42	Y
	Aphid, birch leaf miner		5.28 g/cm of stem basal diameter	n/a	1 (drench)	n/a	
	Birch leaf miner	EC	240 g/L	n/a	2 (paint on)	42	
Camellias	Aphids, mites, camellia scale	SN	28.8 g/10 L	n/a	1 - drench	n/a	Y
			480 g/1000 L; 480 g/ha	960 g/ha	2 -1st yr 1 - next yr	42	
		EC	28.8 g/10 L	n/a	1 - drench	n/a	
			480 g/1000 L; 480 g/ha	960 g/ha	2 – 1st year 1 - next year	42	
Carnations	Aphids, thrips, mites	SN	6.0 kg/ha (drench)	6.0 kg/ha	1	n/a	Y
			480 g/ha	480 g/ha			
		EC	6.0 kg/ha	6.0 kg/ha			
			480 g/ha	480 g/ha			
Day lilies	Aphids, thrips	SN, EC	960 g/1000 L; 960 g/ha	960 g/ha	1	n/a	Y
Euonymus	Aphids, scales	SN, EC	960 g/1000 L; 960 g/ha	2880 g/ha	3	14	Y
Gardenias	Tea scales, whiteflies	SN, EC	480 g/1000 L; 480 g/ha	1440 g/ha	3	14	Y
	whiteflies						
Gerberas	Thrips	SN, EC	480 g/1000 L; 480 g/ha	480 g/ha	1	n/a	Y
Gladioli	Aphids, thrips	SN, EC	480 g/1000 L; 480 g/ha	480 g/ha	1	n/a	Y
Hemlock	Mites, scales, spruce needle miner	SN	480 g/1000 L	1440 g/ha	3	14	Y

Site(s)	Pest(s)	Formulation Type[1]	Application Rate[2] a.i.		Max. # of Applications/ Season[3]	Min. Interval Between Applications (days)	Supported Use[4]
			Maximum Single	Maximum Cumulative			
Hemlock, Spruce, Balsam fir	Mites, scales, spruce needle miner, spruce budworm	EC	720 g/ha	2160 g/ha	3	14	Y
Holly (English, American)	Mites, soft scales, holly leaf miner	SN, EC	480 g/1000 L; 480 g/ha	1440 g/ha	3	14	Y
	Mites, soft scales, leaf needle miner						
Irises	Aphids, iris borer, thrips	SN, EC	960 g/1000 L; 960 g/ha	960 g/ha	1	n/a	Y
Juniper	Aphids, bagworms, midges, mites	SN, EC	960 g/1000 L	2880 g/ha	3	14	Y
Larch	Cone maggot, seed wasps	SN, EC	2.4 kg/1000 L	2.4 kg/ha	1	n/a	Y
Lilac (Syringa spp)	Leaf miners	SN	600 g/1000 L	1200 g/ha	2	42	Y
		EC		1800 g/ha	3		
			240 g/L	n/a (paint on treatment)	2		
Poinsettias (outdoor plants)	Aphids, whiteflies, mites, mealy bugs	SN, EC	480 g/1000 L; 480 g/ha	480 g/ha	1	n/a	Y
Roses	Aphids, leafhoppers, mites, thrips	SN, EC	480 g/1000 L; 480 g/ha	1440 g/ha	3	28	Y
Roses (outdoor plants)	Aphids, leafhoppers, mites, thrips	EC	480 g/1000 L; 480 g/ha	1440 g/ha	3	28	Y
			240 g/L	n/a (paint on treatment)		not stated	
Taxus	mites, Fletcher scale, mealy bugs	EC	960 g/1000 L; 960 g/ha	2880 g/ha	3 (2-for Fletcher scale)	14 (2 for Fletcher scale)	Y
					3	14 (10-for Fletcher scale)	
Taxus (yew)	mites, Fletcher scale, mealy bugs	SN	960 g/1000 L; 960 g/ha	2880 g/ha	3	14 (10 days for Fletcher scales)	

Site(s)	Pest(s)	Formulation Type[1]	Application Rate[2] a.i.		Max. # of Applications/ Season[3]	Min. Interval Between Applications (days)	Supported Use[4]
			Maximum Single	Maximum Cumulative			
Use-site Category 13: Terrestrial Feed Crops **Use-site Category 14: Terrestrial Food Crops**							
Cereals (barley, oats, wheat, rye)	Grasshoppers-adults	EC	408-480 g/ha	816-960 g/ha	2	5	Y
	Grasshoppers-nymphs, Say stink bug		264 g/ha	528 g/ha			
	Aphids		204 g/ha	408 g/ha			
	Thrips		480 g/ha	960 g/ha			
	Orange wheat blossom midge, Russian wheat aphid (wheat only)						
Wheat	Orange wheat blossom midge, Say stink bug	SN, EC	480 g/ha	960 g/ha	2	3	Y
	Orange wheat blossom midge, Russian wheat aphid						
	Orange wheat blossom midge, Say stink bug						
Wheat, Oats, Barley	Thrips	SN, EC	480 g/ha	960 g/ha	2	5	Y
	Aphids		204 g/ha	408 g/ha			
Use-site Category 13: Terrestrial Feed Crops **Use-site Category 16: Industrial and Domestic Vegetation Control for Non-Food Sites**							
Pastures, Wasteland	Grasshoppers - nymphs	SN, EC	264 g/ha	528 g/ha	2	5	Y
	Grasshoppers - adults		408-480 g/ha	816-960 g/ha			
Use-site Category 4: Forests and Woodlots **Use-site Category 27: Ornamentals Outdoor**							
Birch	Aphids, leaf miners	SN, EC	240 g/1000 L	480 g/ ha	2 (foliar)	42	Y
	Aphid, birch leaf miner		5.28 g/cm of stem basal diameter	n/a	1 (drench)	n/a	
	Birch leaf miner	EC	240 g/ L	n/a	2 (paint on)	42	
Boxwood	Mites, leaf miners, mealy bugs	SN, EC	480 g/1000 L	1440 g/ha	3	14	Y
Cedar	Mites, leaf miners	SN, EC	960 g/1000 L	2880 g/ha	3	14	Y

Site(s)	Pest(s)	Formulation Type[1]	Application Rate[2] a.i.		Max. # of Applications/ Season[3]	Min. Interval Between Applications (days)	Supported Use[4]
			Maximum Single	Maximum Cumulative			
Christmas Trees: Balsam Fir, Spruce, Hemlock, Pine (Mugho, Red, Scots)	Aphids, mites, scales, spruce needle miner, spruce budworm	EC	720 g/1000 L; 720 g/ha	2160 g/ha	3	14	Y
	Bagworms, European pine shoot moth, Nantucket pine tip moth, Zimmerman pine moth		960 g/1000 L	2880 g/ha			
Douglas fir (seed tree)	cone or gall midges, cone moths, seed chalcids, scale midges	SN	1.2-2.4 kg/100 L	n/a	1	n/a	Y
		EC	1.2-2.4 kg/100 L				
			1.2-2.4 kg/100 L		3	14	
			1.2 kg/100 L				
Hemlock	Mites, scales, spruce needle miner	SN, EC	720 g/ha	720 g/ha	1	n/a	Y
	Mites, scale, spruce needle miner	EC	480 g/1000 L	1440 g/ha	3	14	
	Mites, scales, spruce needle miner, spruce budworm						
Hemlock, Spruce, Balsam fir	Mites, scales, spruce needle miner, spruce budworm	EC	720 g/ha	720 g/ha	1	n/a	Y
Oak	Golden oak scale	SN, EC	960 g/1000 L	2880 g/ha	3	14	Y
Pine (mugho, red, Scots)	Aphids, bagworms, European pine shoot moth, Nantucket pine tip moth, Zimmerman pine moth	SN, EC	960 g/1000 L	2880 g/ha	3 (2 for pine shoot moth)	14	Y
	Red and black-headed pine sawfly larvae		480 g/1000 L	1440 g/ha			
Sitka spruce	Sitka spruce weevil	SN, EC	12 kg/1000 L	36 kg/ha	3	14	Y
Spruce (woodland use)	Seed and cone insects	SN, EC	4.992-9.984 kg/1000 L	4.99-9.98 kg/ha	1	n/a	Y
		EC	4.992-9.984 g/L	4.99-9.98 kg/ha			

Site(s)	Pest(s)	Formulation Type[1]	Application Rate[2] a.i.		Max. # of Applications/ Season[3]	Min. Interval Between Applications (days)	Supported Use[4]
			Maximum Single	Maximum Cumulative			
Use-site Category 7: Industrial Oil Seed Crops and Fibre Crops **Use-site Category 13: Terrestrial Feed Crops** **Use-site Category 14: Terrestrial Food Crops**							
Canola (rape)	Aphids, leafhoppers, grasshoppers	SN, EC	408-432 g/ha	1224-1296 g/ha	3	**7**	Y
Flax	Potato aphid	SN	204.96 g/ha	204.96 g/ha	1	n/a	Y
		EC	209.76 g/ha	209.76 g/ha			
			206.4 g/ha	206.4 g/ha			
Soybeans	Spider mites	SN	480 g/ha	960 g/ha	2	**7**	Y
	Spider mites (two-spotted)	EC					
	Aphids, bean beetles, leafhoppers, tarnished plant bug, lygus bugs		336-480 g/ha	1008-1440 g/ha	3		

[1] Formulation types are based on the PMRA Oracle database: EC = Emulsifiable Concentrate or Emulsion, SN = Solution

[2] The typical maximum water volume of spray solution is assumed to be 1000 L/ha, except for fruit trees (pears, peaches, and cherries) which was assumed to be 3000 L/ha, unless otherwise stated on the label.

[3] Bold text is the response received from the registrant for information which was not found on the labels. Italics are information for a use extrapolated by PMRA from one registered Canadian label to another.

[4] Y = use is supported by the registrant; and M = use was registered as a User Requested Minor Use Label Expansion (URMULE); P = the registrant partially support the use.

n/a - not applicable

Appendix III Uses of Dimethoate for Those Site-Pest Combinations of Commercial and/or Restricted Class products That Are Not Supported By the Technical Registrant or for which Risk Concerns Have Been Identified

Site(s)	Pest	Supported Use	Concerns From Risk Assessments	Identification of Risk Assessment Concerns
bok choi	aphids	No	No	N/A
around homes, recreation areas	houseflies	No	Yes	See Section 3.2
garbage cans, animal quarters (empty), food processing plants, warehouses, loading docks, refuse areas	houseflies	Yes	Yes	See Section 3.2
dairy barns, hog pens, calf barns, poultry houses & other farm buildings	houseflies	Yes	Yes	See Section 3.2
Birch	Birch leaf miner, aphids, leaf miners	Yes	Partial	See Section 3.2
Carnations	Aphids, thrips, mites	Yes	Partial	See Section 3.2
Lilac (Syringa spp)	Leaf miners	Yes	Partial	See Section 3.2
Roses (outdoor plants)	Aphids, leafhoppers, mites, thrips	Yes	Partial	See Section 3.2
Pastures, Wasteland	Grasshoppers	Yes	Partial	See Section 3.2
Douglas fir (seed tree)	cone or gall midges, cone moths, seed chalcids, scale midges	Yes	Yes	See Section 3.2
Sitka spruce	Sitka spruce weevil	Yes	Yes	See Section 3.2
Spruce (woodland use)	Seed and cone insects	Yes	Yes	See Section 3.2

Appendix IV Label Amendments for Products Containing Dimethoate

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

A submission to request label revisions will be required within 90 days of finalization of the reevaluation decision.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

All the label directions concerning the following uses and application equipment be amended as follows:

- All label directions concerning the application of Dimethoate to Douglas fir seed trees, Sitka spruce, and spruce (woodland use) are proposed for removal;
- All label directions concerning application to structural sites and general outdoor use are proposed for removal;
- All label directions concerning paint-on treatments are proposed for removal;
- Labels should clearly state not to use right-of-way sprayer application equipment;
- Label directions for soil drench application to carnations are proposed for removal.

TOXICOLOGICAL INFORMATION

The following hazard statement should appear on the label of the technical product:

"POISON, DANGER. WARNING: EYE IRRITANT."

Labels of pesticide products carry statements regarding symptoms of poisoning and treatment, which are especially important for those who may be overexposed when working with the product in a commercial or industrial setting for example, mixers/loaders who handle more concentrated forms. Based on the toxicological assessments, the label text of the dimethoate-containing products should be expanded and/or standardized, as follows:

Toxicological Information

"Dimethoate is an organophosphate that is a cholinesterase inhibitor. Typical symptoms of overexposure to cholinesterase inhibitors include headache, nausea, dizziness, sweating, salivation, runny nose and eyes. This may progress to muscle twitching, weakness, tremor, incoordination, vomiting, abdominal cramps and diarrhea in more serious poisonings. A life-threatening poisoning is signified by loss of consciousness, incontinence, convulsions and respiratory depression with a secondary cardiovascular component. Treat symptomatically. If exposed, plasma and red blood cell cholinesterase tests may indicate degree of exposure (baseline data are useful). Atropine, only by injection, is the preferable antidote. Oximes, such as pralidoxime chloride, may be therapeutic if used early; however, use only in conjunction with atropine. In cases of severe acute poisoning, use antidotes immediately after establishing an open airway and respiration. With oral exposure, the decision of whether to induce vomiting or not should be made by an attending physician."

PRECAUTION STATEMENTS

The following label statements are proposed to be added to all labels:

> "Keep the following personal protective equipment immediately available for use in case of emergency (i.e. a broken package, spill, or equipment breakdown): chemical-resistant coveralls, chemical-resistant gloves, chemical-resistant head gear and a respirator."
>
> "Not for use in greenhouses."
>
> "This product is not to be used around homes or other residential areas such as parks, school grounds and/or playing fields. It is not for use by homeowners or other uncertified users."
>
> "Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings."

Engineering Controls and Personal Protective Equipment:
Label statements must be amended (or added) to include the following directions to the appropriate:

A. Mixing/loading liquids (for all uses except forestry):
Wear chemical resistant coveralls over long pants and a long-sleeved shirt, chemical resistant footwear plus socks, chemical resistant gloves, goggles or a face shield and suitable respiratory protection.

B. Mixing/loading liquids (forestry):
Use a closed system for aerial mixing/loading for forestry use (hemlock, spruce and balsam fir). Wear cotton coveralls over long pants and a long-sleeved shirt, chemical resistant footwear plus socks, chemical resistant gloves, goggles or a face shield.

C. Applying by air:
Wear cotton coveralls over long pants and a long-sleeved shirt, shoes plus socks.

D. Applying by groundboom:

During groundboom application use a closed cab that provides both a physical barrier and respiratory protection (i.e. dust/mist filtering and/or vapour/gas purification system). The closed cab must have a chemical resistant barrier that totally surrounds the occupant and prevents contact with pesticides outside the cab. Wear cotton coveralls over long pants and a long-sleeved shirt, chemical resistant footwear plus socks. Chemical resistant gloves are not required to be worn while driving closed cab equipment but are required for clean-up and repair activities.

E. Applying by airblast:

During airblast application use a closed cab that provides both a physical barrier and respiratory protection (i.e. dust/mist filtering and/or vapour/gas purification system). The closed cab must have a chemical resistant barrier that totally surrounds the occupant and prevents contact with pesticides outside the cab. Wear cotton coveralls over long pants and a long-sleeved shirt, chemical resistant footwear plus socks. Chemical resistant gloves are not required to be worn while driving closed cab equipment but are required for clean-up and repair activities.

If a closed cab is not feasible, wear chemical resistant coveralls over long pants and a long-sleeved shirt, chemical resistant footwear plus socks, chemical resistant gloves and chemical-resistant headgear. Chemical resistant headgear includes so'westers, or large brimmed, water-proof hats, and hoods with sufficient neck protection. Avoid touching face or other unprotected parts of the body during application.

F. Applying by handheld equipment:

Wear chemical resistant coveralls over long pants and a long-sleeved shirt, chemical resistant footwear plus socks, chemical resistant gloves and suitable respiratory protection. Limit the amount of active ingredient handled per day to 2.8 kg per person (for example, approximately 2950 L at a rate of 0.96 g a.i./L) when applying by handheld equipment.

G. Applying by soil drench, soil injection or chemigation:

Wear chemical resistant coveralls over long pants and a long-sleeved shirt, chemical resistant footwear plus socks, chemical resistant gloves and suitable respiratory protection.

Add to ENVIRONMENTAL HAZARDS:

TOXIC to bees. Bees can be exposed to product residues in flowers, leaves, pollen and/or nectar resulting from soil and foliar applications.

TOXIC to certain beneficial insects. Minimize spray drift to reduce harmful effects on beneficial insects in habitats next to the application site such as hedgerows and woodland.

TOXIC to birds, mammals and aquatic organisms. Observe buffer zones specified under DIRECTIONS FOR USE.

To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to: heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (for example, soils that are compacted or fine textured such as clay).

Avoid application of this product when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

Add to DIRECTIONS FOR USE:

Maximum Spray Volume:

Where maximum spray volume for fruit trees (pears, peaches, cherries) is not specified the following statement should be added to labels:

"Apply at the recommended rate; do not exceed a maximum spray volume of 3000 L per hectare unless otherwise stated."

And the following statement should be added to all other labels:

"Apply at the recommended rate; do not exceed a maximum spray volume of 1000 L per hectare unless otherwise stated."

Number of Applications:

Consult Table 1 below for the number of applications and application intervals recommended per crop:

Table 1 Recommended Maximum Number of Applications per Year and Minimum Application Intervals

Crop	Maximum Number of Applications per Year	Minimum Application Interval (Days)
alfalfa, asparagus, beets, beet greens, bok choi, broccoli, brussel sprouts, canola, cauliflower, celery, cereals (barley, oat, wheat and rye), chicory, Chinese broccoli, clover (sweet, red, alsike), eggplant, forage crops, grains, lettuce, pastures, peppers, potatoes, safflower, soybeans, Swiss chard, tomatoes, turnip greens, wastelands	2[a]	7[b]
camellias, lilac, peaches, pears, roses	2[a]	10[b]
birch, blueberries (high and low bush), cherries, flax, hazelnuts (filberts), larch	No change required	
arborvitae, azalea, beans, boxwood, cedar, euonymus, gardenias, holly (English, American), juniper, oak, pea	2[a]	14[d]
ornamental and forestry use (ground application): hemlock, pine (mugho, red, Scots) Christmas trees (Balsam fir, spruce, hemlock, mugho pine, red pine, Scot pine)	2[a]	14[d]
forestry use (restricted aerial): balsam fir, hemlock, spruce	1[c]	Not applicable
carnation, day lilies, gerberas, gladioli, irises, poinsettias	1[c]	Not applicable
canary grass	2[a]	30[d]
kale	2[a]	15[d]
strawberry	2[a]	10[b,d]
Taxus	2[a]	14[b,d]

[a] Maximum number of applications per year, unless one application is currently stated on labels.

[b] Minimum interval between applications (days), unless a longer interval is currently stated on labels.

[c] Maximum number of applications supported by registrant.

[d] Minimum application interval supported by registrant.

The following pre-harvest intervals (PHI), pre-grazing intervals (PGI), plant back intervals and application rates need to be revised:

Crop	Proposed Label Revisions for Commercial Products
All Crops/Labels	30 days plant interval for fields treated with Dimethoate
Alfalfa	Minimum 10 days pre-harvest interval (PHI)/pre-grazing interval (PGI)
Asparagus	Dimethoate should be applied post harvest only
Blueberry	Minimum 21 days PHI
Broccoli, Cauliflower	Minimum 7 days PHI
Celery	Minimum 7 days PHI
Cereals (wheat, barley, rye, oats)	Minimum 14 days PGI and 35 days PHI
Kale, Lettuce (leaf), Swiss Chard, Turnip (greens)	Minimum 14 days PHI
Peach (non-bearing)	Minimum 40 days PHI
Peas	Maximum rate reduced to 0.18 kg a.i./ha
Pear	Maximum rate reduced to 1.44 kg a.i./ha Minimum 28 days PHI
Potato, Tomato	Maximum rate reduced to 0.48 kg a.i./ha

RESTRICTED-ENTRY INTERVAL:

The restricted-entry intervals listed in Table 2 below must be added to the appropriate labels. Where deemed necessary, REIs are sub-divided according to re-entry activities.

Table 2 Recommended Restricted-entry Intervals

Crops	Activity	Proposed REI [a] (days)
Filberts (hazelnuts)	Thinning	34
	Hand harvesting, hand-line irrigation	21
	All other activities	5
Peaches	Thinning	32
	Hand harvesting, hand-line irrigation	20
	All other activities	3
Pears	Thinning	28
	Hand harvesting, hand-line irrigation	17
	All other activities	1
Cherries	Thinning	20
	Hand harvesting, hand-line irrigation	9
	All other activities	12 hrs
Blueberries	Hand harvesting (high bush)	12
	Hand harvesting (low bush) and all other activities	12 hrs
Boxwood	Thinning	7
	All other activities	12 hrs
Hemlock, spruce, Balsam fir	Thinning	13
	All other activities	12 hrs
Christmas trees (Balsam fir, spruce, hemlock, pine), pine, oak, cedar	Thinning	18
	Hand-line Irrigation	3
	All other activities	12 hrs
Lilac	All activities	15
Holly	All activities	12
Day lilies, irises	All activities	7
Broccoli, cauliflower	All activities	5
Bok choi, chicory, Chinese broccoli	All activities	4

Crops	Activity	Proposed REI [a] (days)
Leaf vegetables (beets and beet greens, turnip greens, kale, lettuce, celery)	All activities	3
Azaleas, camellias, carnations, gerberas, gladioli, poinsettias, roses, brussel sprouts, strawberries	All activities	2
Larch	All activities	1
All other crops, soil drench or injection and chemigation application	All activities	12 hours

[a] Day at which the dermal exposure results in an MOE $\geq$100.

Field sprayer application:

DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) fine classification. Boom height must be 60 cm or less above the crop or ground.

Airblast application:

DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated.

Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

Aerial application:

DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured from a height of two metres off the ground. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) fine classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length **MUST NOT** exceed 65% of the wing- or rotorspan.

Buffer zones:

Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer, or spot treatment.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Crop		Buffer Zones (metres) Required for the Protection of :			
			Freshwater habitat of Depth:		Estuarine/Marine habitats of Depth:	
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
Field sprayer*	Cereals, wheat, forage crops, strawberries, vegetables, asparagus, potatoes, tomatoes, flax, clover		1	1	2	1
	Flowering plants		3	1	4	2
Airblast	Christmas trees, ornamentals	Early growth stage	10	4	15	5
		Late growth stage	5	2	5	3
	Fruit trees	Early growth stage	15	10	20	10
		Late growth stage	10	4	10	5
	Woodland	Early growth stage	30	20	30	25
		Late growth stage	20	10	25	15
	Sitka spruce	Early growth stage	35	25	40	30
		Late growth stage	25	20	30	20

Method of application	Crop		Buffer Zones (metres) Required for the Protection of :			
			Freshwater habitat of Depth:		Estuarine/Marine habitats of Depth:	
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
Aerial	Flax	Fixed wing	1	0	1	0
		Rotary wing	1	0	1	0
	Cereals, forage crops, wheat	Fixed wing	5	1	10	1
		Rotary wing	4	1	10	1
	Clover	Fixed wing	10	1	15	1
		Rotary wing	5	1	10	1
	Shrubs and trees	Fixed wing	35	1	50	15
		Rotary wing	20	1	30	5
	Forestry hemlock, spruce, balsam fir)	Fixed wing	90	1	150	15
		Rotary wing	55	1	90	2

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

Appendix V Toxicology Profile for Dimethoate

Notes: 1) Depression of PChE is not considered by PMRA to be a toxicologically adverse effect; it can be viewed as a marker of exposure. Depression of EChE can be viewed as a surrogate for adverse changes in peripheral nervous tissue in acute and some short-term studies. In studies of longer duration, depression of EChE alone is not considered by PMRA to be a toxicological adverse effect.

2) Effects noted below are known or assumed to occur in both sexes unless otherwise specified.

Study/Species/ Animal#	**Purity of A.I./ Dose Level**	**Results**	
		NOAEL (mg/kg bw/day)	**Effects**
Metabolism/Toxicokinetics			
Absorption, distribution, excretion and metabolism - rats	^{14}C-Dimethoate (labeled on the O-methyl groups) Single radiolabelled oral dose: 10 or 100 mg/kg bw; Single radiolabelled intravenous dose: 10 mg/kg bw; 14-day repeated oral dose: 10 mg/kg bw/day of unlabelled Dimethoate for 14 days, followed by a single oral radiolabelled dose of 10 mg/kg bw.	No remarkable sex-, dose- or treatment-related differences in the absorption, distribution, and elimination. **Absorption**: Readily absorbed **Distribution**: No evidence of bioaccumulation; the tissue retention was 7 ppm after a single oral high dose at 100 mg/kg bw, or 0.3 ppm after 10 mg/kg bw/day (single oral, multiple oral or intravenous dose), but the exact time of measurements after dosing was not provided. **Excretion**: Rapidly eliminated; 91- 97% of the administered dose was recovered in urine for all tested groups within 5 days after dosing (urine: 85-91% of the dose; feces: 1-2%; expired air as CO_2: 2-3%: carcass: 1-2%). **Metabolites**: Metabolites were excreted mainly via the urine and were identified as: Omethoate (1-6% of the dose), dimethylthiophosphoric acid (4-11% of the dose), dimethyldithiophosphate (20-30% of the dose) and Dimethoate carboxylic acid (29-46% of the dose). Unchanged parent compound in the urine ranged 0.4-2% of the dose. **Metabolic pathway**: The proposed metabolic pathway consisted of hydrolytic (major) and oxidative (minor) pathways. The hydrolytic pathway involved cleavage of the C-N bond to yield Dimethoate carboxylic acid that was subsequently metabolized to dimethyldithiophosphate, dimethylthiophosphoric acid and dimethyl phosphoric acid. The oxidative pathway involved oxidation of Dimethoate to its oxon analogue (Omethoate) that was subsequently metabolized to dimethylthiophosphoric acid and dimethylphosphoric acid. Loss of the methoxy groups of the parent to yield CO_2 was another minor metabolic pathway.	

Study/Species/ Animal#	Purity of A.I./ Dose Level	Results	
		NOAEL (mg/kg bw/day)	Effects
Absorption, distribution or excretion - rats, cats and humans (2 studies combined)	Purity not available • Single labelled (^{32}P-Dimethoate) oral dose: the actual dose not provided in rat & human studies • Single oral dose: 50, 75, or 200 mg/kg bw (cats), and 300 mg/kg bw (rats). • Repeated daily oral dose: 10 or 20 mg/kg bw/day in both cats and rats (the number of dosing days not specified).	**Single labelled oral dose**: Rapidly absorbed from the gastrointestinal tract. In treated animals, the radiolabel was found in the liver, bile, kidneys and urine, and not in fat tissues after dosing. Elimination was rapid in rats and humans, 76-90% of the radiolabel being found in the urine after 24 h. **Single oral dose**: Dimethoate was detected in the blood of rats and cats after 30 min and reached a maximum after 60-90 min post treatment. Nearly 80% of Dimethoate in the blood was found in the erythrocytes of both species, and only 15-20% was found in the serum. **Repeated daily oral dose**: Maximum blood levels of Dimethoate occurred on days 5-10 (the total number of dosing days not provided).	
Excretion - rats	Purity not available Single labelled (^{32}P-Dimethoate) oral or dermal dose: 50 mg/kg bw	About 45% and 5.8% of the radiolabelled Dimethoate administered orally were excreted in the urine and the feces, respectively, at 72 h after treatment. The equivalent values in rats after dermal application were 31% and 6.5%, respectively. More than 95% of excreta in the urine after the oral or dermal administration to rats were hydrolytic products.	
Metabolism - rat liver homogenate	Radiolabelled Dimethoate (on dimethyl or phosphorodithioic position) In vitro exposure for 5 hours	The oxygen analogue (Omethoate) was proposed as one metabolite, and cleavage of the C-N bond to produce the carboxyl derivative was said to be a major pathway, along with the hydrolysis of the S-C bond to produce O, O-dimethylphosphorodithioc acid. Dimethyl and monomethylphosphoric acid and thiophosphoric acid may also be produced. Most of the non-phosphorus part of the molecule was reported to become conjugated with glucuronic acid.	
Acute Toxicity			
Acute oral toxicity -various species	95 - 99% pure	Rat LD$_{50}$ = 310 - 600 mg/kg bw Mouse LD$_{50}$ = 160 mg/kg bw Clinical signs included muscular fibrillation, salivation, lacrimation, urinary incontinence, diarrhea, respiratory distress, prostration, gasping, coma and death occurring at 0.5-2 h after dosing. **HIGH OR MODERATE TOXICITY**	
Acute dermal toxicity - various species	96-99% pure	LD$_{50}$>2000 mg/kg bw (rabbit and rat) Clinical signs of toxicity included hunched posture, abnormal gait (waddling) subsiding by day 13. **LOW TOXICITY**	

Study/Species/ Animal#	Purity of A.I./ Dose Level	Results	
		NOAEL (mg/kg bw/day)	Effects
Acute inhalation toxicity - rats	95% pure	LC_{50}>2 mg/L **LOW TOXICITY**	
Eye irritation - NZW rabbits	96-98% pure	Moderate eye irritation (cornea, iris and conjunctivae) with recovery by day 7	
Dermal irritation - NZW rabbits	96-98% pure	Minimal irritation - slight erythema and edema with recovery by day 2	
Dermal sensitization - Hartley guinea pigs	97.3% pure	Negative (by a closed patch technique, similar to Buehler)	
Subchronic Toxicity			
5-day dermal toxicity - Sprague Dawley rats (16/sex/dose)	43.5% a.i.(w/w) 2-42 µl Dimethoate 4 E formulation/animal (= 0, 5, 10, 20, 40 or 100 mg a.i./kg bw/day), 6 hrs/day for 5 days	10 mg/kg bw/day (♀) 40 mg/kg bw/day (♂)	≥20 mg/kg bw/day: ↓BChE, EChE and PChE (♀) 100 mg/kg bw/day: desquamation and ↓BChE and EChE (♂), clinical signs (ptosis in ♂; tremors, shallow breathing pale eyes, exophalmus and excessive lacrimation in ♀)
28-day dermal toxicity - Wistar rats (10/sex/dose)	38% a.i. (w/w) 0, 0.0263, 0.0525, 0.0788 or 0.1575 ml Dimethoate 400 g/L EC/kg bw/day (= 0, 10.5, 21.0, 31.5 or 63.0 mg a.i./kg bw/day) for 6 hrs/day, 5 days/week for 4 weeks	10.5 mg/kg bw/day $BMDL_{10}$ for BChE inhibition: 18.7 - 35.2 mg/kg bw/day	≥21.0 mg/kg bw/day: ↓BChE 63.0 mg/kg bw/day: ↓ EChE
13-week dietary toxicity - Sprague Dawley rats (10/sex/dose)	95% pure 0, 2, 8, 32 or 400* ppm (= 0, 0.1, 0.4, 1.6 or 20 mg/kg bw/day) for 13 weeks + 50 ppm (2.5 mg/kg bw/day) for 4 weeks. *400 ppm group: given 100 ppm for 12 days, 200 ppm for 7 days and then 400 ppm for 74 days (♂) or 73 days (♀).	1.6 mg/kg bw/day	≥2.5 mg/kg bw/day: ↓BChE, EChE & PChE at ≥weeks 4 20 mg/kg bw/day: ↓body weight gain, ↓food consumption, ↑relative liver and kidney weight

Study/Species/ Animal#	Purity of A.I./ Dose Level	Results	
		NOAEL (mg/kg bw/day)	**Effects**
Chronic Toxicity/Oncogenicity			
One year dietary toxicity - Beagle dogs 6 /sex/dose	96.4% pure 0, 5, 20 or 125 ppm (= 0, 0.19, 0.73 or 4.25 mg/kg bw/day)	0.19 mg/kg bw/day	≥0.73 mg/kg bw/day: ↓BChE and EChE 4.25 mg/kg bw/day: ↓PChE
2-year dietary chronic toxicity & carcinogenicity - Wistar rats (65/sex/dose + 20/sex at 1 ppm for ChE assessments)	96.7% pure 0, 5, 25 or 100 ppm (= 0, 0.25, 1.25 or 5 mg/kg bw/day), and an additional dose, 1 ppm (0.05 mg/kg bw/day) for the ChE assessment	0.05 mg/kg bw/day BMDL$_{10}$ for BChE inhibition: 0.22 - 0.31 mg/kg bw/day	≥0.25 mg/kg bw/day: ↓BChE and EChE, ↑incidence of vascular tumors (combined hemangioma and hemangiosarcoma in the spleen, lymph node and skin) ≥1.25 mg/kg bw/day: ↓PChE 5 mg/kg bw/day: transiently ↓body weight gain (♂); ↑mortality (♀ only near end of the study), ↑anemia (♂), ↑leukocytes. **EQUIVOCAL EVIDENCE OF CARCINOGENICITY**
18-month dietary oncogenicity - B6C3F1 mice 50/sex/dose	≥96.7% pure 0, 25, 100 or 200 ppm (= 0, 3.75, 15 or 30 mg/kg bw/day)	3.75 mg/kg bw/day (LOAEL)	≥3.75 mg/kg bw/day: ↓PChE and EChE (BChE not measured); ↓absolute and relative ovary weights (♀) at one period only (after 72 weeks); ↓body weight gain (♂), ↑hepatic vacuolation ≥15 mg/kg bw/day: ↑absolute liver weights 30 mg/kg bw/day: transiently ↓body weight gain (♀ in the first 2 weeks only). **NO EVIDENCE OF CARCINOGENICITY**

Study/Species/ Animal#	Purity of A.I./ Dose Level	Results	
		NOAEL (mg/kg bw/day)	Effects
Neurotoxicity			
Acute delayed neurotoxicity - 30 Leghorn hens	96.4% pure Single oral dose 55 mg/kg bw (LD_{50}) on day 0, followed by a similar dose and treatment on day 21 (no atropine protection)		Negative for acute delayed neurotoxicity Mortality (12/30 birds died within 48 h of dosing), subdued appearance, unsteadiness, occasional stumbling and inability to stand during days 0-6; ↓body weight on days 0-7, but subsequently recovery and gain; ↓BChE and ↓brain NTE (not biologically significant), but no effects in spinal cord NTE. Survivors showed no clinical signs of delayed acute neurotoxicity (delayed motor ataxia) and no treatment-related histological changes in nerve tissues.
Acute dietary neurotoxicity study - Sprague Dawley rats (24/sex/dose: 16/sex/dose for FOB & motor activity evaluations + 8/sex/dose for ChE evaluations)	99.1% pure 0, 1, 2, 3 or 15 mg/kg bw	2 mg/kg bw	3 mg/kg bw: ↓BChE (♀ only, days 1 and 15 sacrifices), ↓EChE (♂ on day 1), ataxia (1/24 ♀ at day 1). 15 mg/kg bw: ↓BChE (days 1 & 15), ↓EChE (day 1), tremors (1/sex at day 1). Note: a histological examination of nervous tissues was not conducted and no data was available for day 7
Acute oral (gavage) neurotoxicity - Sprague Dawley rats (12/sex/dose)	99.1% pure 0, 2, 20 or 200 mg/kg bw in water	2 mg/kg bw	≥20 mg/kg bw: ↑incidences of an absence of pupil response. 200 mg/kg bw: ↓body weight, ↓motor activity, ↓body temperature, tremors, motor and sensory function affected. Note: ChE activity not measured
13-week dietary neurotoxicity - Sprague Dawley rats (10-12/sex/dose)	99.1% pure 0, 1, 50 or 125 ppm (≈0, 0.06, 3.22 or 8.13 mg/kg bw/day for ♂ and 0, 0.08, 3.78 or 9.88 mg/kg bw/day for ♀)	3.22 mg/kg bw/day	≥3.22/3.78 mg/kg bw/day: ↓EChE and PChE 8.13/9.88 mg/kg bw/day: ↓BChE (olfactory, midbrain, brainstem, cerebellum and cortex)

Study/Species/ Animal#	Purity of A.I./ Dose Level	Results	
		NOAEL (mg/kg bw/day)	**Effects**
Range-finding oral (gavage) developmental neurotoxicity - CD rats (10 pregnant ♀/dose)	99.1% pure 0, 0.1, 0.2, 0.5, 3.0 or 6.0 mg/kg bw/day from gestation day (GD) 6 to PND 10 followed by pup direct dosing PND 11-21 (2 pups/sex/litter). Additional 5 ♀/dose treated from GD 6-20 for ChE determination	0.2 mg/kg bw/day (maternal and offspring) 3.0 mg/kg bw/day (developmental) $BMDL_{10}$ for BChE inhibition: 0.2 - 0.4 mg/kg bw/day for dams, fetuses and pups)	**Maternal**: ≥3.0 mg/kg bw/day: ↓maternal weight gain during gestation, ↓BChE, EChE and PChE (GD 20) **Developmental/reproductive**: 6.0 mg/kg bw/day:↓pup weight at birth (PND 1) **Offspring**: ≥3 mg/kg bw/day: ↓BChE, EChE , and PChE at PND 21, ↓ fetal BChE, EChE, and PChE at GD 20 6.0 mg/kg bw/day: ↑mortality and total litter loss in PNDs 1-4, ↓viability index at PND 4 (precull) |,↓pup weight gain (PNDs 1-11) Note: Due to small sample size, parameters were not analysed statistically except body weight; considered supplemental
Oral (gavage) developmental neurotoxicity (special ChE assessments) - CD rats (8-10 pregnant ♀/dose)	99.1% pure 0, 0.1, 0.5 or 3.0 mg/kg bw/day Acute exposure: 8 PND 11 pups or 8 adults/dose Repeat exposure: 9 pregnant ♀/dose from gestation days (GDs) 6 - 20 and terminated, 10 pregnant ♀/dose from GD 6 to PND 10 followed by 1/sex/litter offspring treated from PNDs 11-21, or 8 adults/dose for 11 days	0.5 mg/kg bw (**acute** exposure in adults and pups) 0.1 mg/kg bw/day (**repeat** exposure in fetuses, maternal, adults and pups) $BMDL_{10}$ for BChE inhibition: 1.3 - 2 mg/kg bw (**acute** exposure in adults and pups) 0.2 - 0.7 mg/kg bw/day (**repeat** exposure in fetuses, maternal, adults and pups)	**Acute exposure** 3.0 mg/kg bw/day: ↓BChE (PND 11 pups and adults), ↓EChE (adult ♀), ↓PChE (adult ♂, PND 11♂ pups) **Repeat exposure** **Maternal/adult** ≥0.5 mg/kg bw/day: ↓BChE (GD 20) 3.0 mg/kg bw/day: ↓EChE and PChE (GD 20) **Fetal/Offspring** ≥0.5 mg/kg bw/day: ↓BChE (fetuses, PND 21 pups), ↓EChE (PND 21 ♀ pups) 3.0 mg/kg bw/day: ↓BChE (PND 4 ♂ pups), ↓EChE (fetuses, PNDs 4 and 21 ♂ pups)

Study/Species/ Animal#	Purity of A.I./ Dose Level	Results	
		NOAEL (mg/kg bw/day)	Effects
Oral (gavage) developmental neurotoxicity (main study) - CD rats (24 mated ♀/dose	99.1% pure 0, 0.1, 0.5 or 3.0 mg/kg bw/day in water from gestation day (GD) 6 to postnatal day (PND) 10, and direct exposure to offspring during PNDs 11-12	0.1 mg/kg bw/day (offspring) 3.0 mg/kg bw/day (maternal & developmental)	**Maternal**: no adverse effects **Developmental/reproductive**: no treatment-related effects **Offspring**: ≥0.5 mg/kg bw/day: ↑mortality, ↑total litter loss (PNDs 1-4), ↑horizontal activity (PND 17 in ♂) 3.0 mg/kg bw/day: ↓motor activity counts (PND 21), ↓ righting reflexes (PND 11 in ♀) and rearing (PND 17 in ♀) Note: ChE not measured in this study, see ChE data in the above comparative cholinesterase study
Developmental and Reproductive Toxicity			
Developmental toxicity (gavage) - Sprague Dawley rats (25 mated ♀/dose)	97.3% pure 0, 3.0, 6.0 or 18.0 mg/kg bw/day in 1% methyl-cellulose on days 6 - 15 of gestation	6.0 mg/kg bw/day (maternal) 18 mg/kg bw/day (developmental)	**Maternal** 18.0 mg/kg bw/day: salivation, hypersensitivity, unsteady gait, body tremors, brown fur staining and abnormal feces; ↓maternal body weight gains and food consumption **Developmental** None Note: ChE not measured **NO EVIDENCE OF TERATOGENICITY**
Developmental toxicity (gavage) - New Zealand White rabbits (16 pregnant ♀/dose)	97.3% pure 0, 10, 20, or 40 mg/kg bw/day on days 6-18 of gestation	10 mg/kg bw/day (maternal) 20 mg/kg bw/day (developmental)	**Maternal** ≥20 mg/kg bw/day: ↓maternal weight gain 40 mg/kg bw/day: ↓food consumption, ↑muscle tremors and ataxia **Developmental** 40 mg/kg bw/day: ↓fetal weight Note: ChE not measured **NO EVIDENCE OF TERATOGENICITY**

Study/Species/ Animal#	**Purity of A.I./ Dose Level**	**Results**	
		NOAEL (mg/kg bw/day)	**Effects**
2-generation, 2-litter per generation reproductive toxicity - Sprague Dawley rats (24-28/sex /dose)	96.4% pure 0, 1, 15 or 65 ppm (0, 0.08, 1.2 or 5.46 mg/kg bw/day in ♂, or 0, 0.09, 1.3 or 6.04 mg/kg bw/day in ♀)	0.08/0.09 mg/kg bw/day, ♂/♀ (parental toxicity) 1.2/1.3 mg/kg bw/day, ♂/♀ (reproductive and offspring toxicity) $BMDL_{10}$ for BChE inhibition: 0.3 - 0.7 mg/kg bw/day	**Parental** ≥1.2/1.3 mg/kg bw/day: ↓BChE and EChE 5.46/6.04 mg/kg bw/day: ↓PChE **Reproductive** 5.46/6.04 mg/kg bw/day: ↓fertility (both generations), ↓litter size (day 1 after birth). **Offspring** 5.46/6.04 mg/kg bw/day: ↓BChE, ↓weight gains and ↑mortality
2-generation, 2-litter per generation reproductive toxicity Wistar rats 25 /sex/dose	99.1% pure 0, 0.2, 1.0 or 6.5 mg/kg bw/day BChE measured in pups of the controls and 6.5 mg/kg/day groups only	0.2 mg/kg bw/day (parental toxicity) 6.5 mg/kg bw/day (reproductive toxicity) 1.0 mg/kg bw/day (offspring toxicity) $BMDL_{10}$ for BChE inhibition: 0.2 - 0.5 mg/kg bw/day	**Parental** ≥1.0 mg/kg bw/day: ↓BChE; ↓EChE (♂) 6.5 mg/kg bw/day: ↓lactational weight gains in F1 ♀; focal vacuolization of epididymides in P and F_1 ♂, ↓ prostate weights, ↓secretion of prostate, ↑vacuolization of cauda epididymides and diffuse epithelial atrophy of prostate gland in F_1 ♂ **Reproductive** Reproductive performance unaffected. **Offspring** 6.5 mg/kg bw/day: ↓weight gain in F_{1b}; ↓BChE in F_{1b} ♀ PND 4 pups (↓10%) (no effect seen in F_{1b} PND 4 ♂ pups, or in F_{2b} PND 4 ♂/♀ pups).
Cross-fostering Crl:CD®BR 100, 25 and 50 dams in control, 3 and 6 mg/kg bw/day groups resp.	99.1% pure 0, 3 or 6 mg/kg bw/day to dams from gestation day 6 to post-natal day 10, litters cross-fostered on PND 1 as follows: control litters (¼ reared by their own control dam, ¼ to each of 3 and 6 mg/kg groups and ¼ discarded), 3 mg/kg litters (all to control), 6 mg/kg litters (½ to control and 6 mg/kg groups resp.)	LOAEL = 3 mg/kg bw/day (maternal and offspring toxicity)	**Maternal** 3 mg/kg bw/day: forelimb hairloss, marginal ↓weight gain, ↑restlessness and scattering of pups **Offspring** 3 mg/kg bw/day: ↓milk consumption, ↑blood urea, slight ↑mortality 6 mg/kg bw/day: ↑mortality, ↑hematocrit, ↑MCV, ↓MCHC, ↑ neutrophils, ↑monocytes, ↓creatine phosphokinase; ↓surface righting reflex on PND 10, ↓weight gain PND1-11 (post-natal treatment only

Study/Species/ Animal#	Purity of A.I./ Dose Level	Results	
		NOAEL (mg/kg bw/day)	Effects
Genotoxicity			
Ames test S. typhimurium TA98, TA100, TA1535, TA1537, TA1538 and E. coli WP-2uvrA$^-$	Up to 10,000 µg/plate		Negative
Ames test S. typhimurium TA98, TA100, TA1535, & TA1537	Doses not specified		Negative
Reverse mutation S. typhimurium TA98, TA100, TA1535, TA1537 & TA1538; E. coli WP2uvrA−	≤5000 µg/plate (S. typhimurium) 47 nmol/ml (E. coli):		Negative
Chinese hamster ovary (CHO)/HGPRT gene mutation	97.3% pure 0, 1000, 1500, 2000, 2700 or 3500 µg/ml		Negative.
Dominant lethal assay - mice (5 ♂/dose)	5, 10 or 20 mg/kg bw/day for 5 days by gavage; 96.9% pure.		Negative
In vivo bone marrow cytogenic assay - Sprague Dawley rats	97.3% pure 0, 15, 75 or 150 mg/kg bw, ip.		Negative
Micronucleus assay - mice (5/sex/group)	97.3% pure 55 mg/kg bw ip once or twice 24 h apart		Negative
In vivo unscheduled DNA synthesis - Wistar male rats	96.4% pure Single oral dose: 0, 50, 100 or 200 mg/kg bw in corn oil by oral gavage		Negative

Study/Species/ Animal#	Purity of A.I./ Dose Level	Results	
		NOAEL (mg/kg bw/day)	Effects
In vitro unscheduled DNA synthesis - rat hepatocytes	47 nmol/ml		Negative.
In vitro unscheduled DNA synthesis - rat hepatocytes	96.3% pure Exp. 1): 7.63, 22.9, 76.3, 229, 763 or 2290 µg/ml Exp. 2): 23, 76, 229, 763 or 2290 µg/ml		Positive: ≥763 µg/ml (cytotoxic at ≥736 µg/ml)
Omethoate (the oxygen analogue of Dimethoate)			
Metabolism/Toxicokinetics - Omethoate			
Absorption, distribution and excretion - Wistar rats (5/sex/dose)	• Single labelled (^{14}C-Omethoate) oral or intravenous dose of 0.5 mg/kg bw • 14 daily unlabelled oral doses of 0.5 mg/kg bw, followed by a single oral labelled dose of 0.5 mg/kg bw on day 15 • Single oral labelled dose of 10 mg/kg bw	**Absorption**: >98% absorbed from GI tract. **Distribution:** Tissue retention was <0.05% of administered doses 48 h post treatment; highest levels occurred in plasma 40-60 min after oral dosing with an initial half-life of about 2 h and terminal half-life of 13-28 h. **Excretion:** Within 48 h, 95-98% of the administered dose was recovered in the urine and 2-5% in the feces. Excretion of low and high doses was not different in females, but males at the high dose group tended to excrete more radiolabel in the feces than those at the low dose.	
Excretion and metabolism - Sprague Dawley rats (4 ♂)	Single oral labelled dose: 5 mg/kg bw in 5% aqueous cremophor	**Excretion:** 88% of administered dose found in the urine 8 hrs after dosing **Metabolites:** Identified metabolites mainly found in the urine as unchanged Omethoate (26 or 44% of administered dose in the first 8 hrs), O-desmethylated Omethoate (approx. 9% of the dose), and N-methyl methyl-sulphinyl acetamide (13 or 22% of the dose) and 9 unidentified metabolites.	
Acute Toxicity Studies - Omethoate			
Acute oral toxicity -mice, rats and rabbits	-	Mouse LD$_{50}$ (♂) = 27-36 mg/kg bw. Rat LD$_{50}$ = 22-65 mg/kg bw Rabbit LD$_{50}$ (♂) = 50 mg/kg bw Clinical signs of toxicity were consistent with those of cholinesterase inhibiting chemicals. The onset of signs was 5-25 minutes after dosing and deaths were seen within 45 minutes. In survivors, ↓weight gain was also reported. **HIGH TOXICITY**	
Acute dermal toxicity - Wistar rats	94% pure	LD$_{50}$ = 145 - 232 mg/kg bw Clinical signs of toxicity were consistent with those of cholinesterase inhibiting chemicals.In survivors, weight loss or ↓weight gain was also reported. **HIGH TOXICITY**	

Study/Species/ Animal#	Purity of A.I./ Dose Level	Results	
		NOAEL (mg/kg bw/day)	Effects
Acute inhalation toxicity - Wistar rats	97.4% pure 4 hrs whole-body exposure	LC_{50} = 0.282 mg/L Clinical signs included reduced motility, prostration, laboured breathing, ataxia, clouded and dried cornea and haemorrhagic eyes, dyspnoea and trembling, and ↓weight gain during the first 4 days at ≥0.076 mg/L **MODERATE TOXICITY**	
Dermal irritation - New Zealand White rabbits	96.9% pure	No irritation	
Eye irritation - New Zealand White rabbits	96.9% pure	Moderate irritation - conjunctiva redness persisted up to 72 hrs after treatment	
Dermal sensitization - guinea pigs (2 studies)	95-97% pure various concentrations	Potential dermal sensitizer (by Magnusson and Kligman maximisation test and open epicutaneous test)	
Neurotoxicity Studies - Omethoate			
Acute delayed neurotoxicity (gavage) - hens (10)	92 mg/kg bw (LD_{50}) with atropine protection	Deaths occurred in several hens, but none showed clinical or histological signs indicative of delayed neurotoxicity. Note: neurotoxic esterase not measured	
Acute delayed neurotoxicity (gavage) - hens (4-6/dose)	2-300 mg/kg bw (4-8 times LD_{50} as stated, no details) in corn oil under atropine protection	Mortality (100% at 300 mg/kg bw), and the neurotoxic esterase activity in the brain of the animals that died was found to be normal; acute cholinergic symptoms increased at 20-300 mg/kg bw, correlated with strong inhibition of BChE. Omethoate did not induce delayed neurotoxicity. Note: the histological examination of the nerve tissue not conducted	
Acute delayed neurotoxicity (gavage) - hens (15 in treated group, 5 in positive control, 6 in vehicle control)	96.7% pure 140 mg/kg bw (2 times LD_{50} as stated) in demineralized water under atropine protection, repeated at 21 days	Mortality and clinical signs (apathy, staggering gait, diarrhea, spasms, dry comb, prostration, panting, ruffled feathers) after dosing. Recovery 8 days after first dose, 16 days after second dose. No clinical or histological signs indicative of delayed neurotoxicity.	

Study/Species/ Animal#	**Purity of A.I./ Dose Level**	**Results**	
		NOAEL (mg/kg bw/day)	**Effects**
Acute gavage neurotoxicity - rats (♀)	94% pure 0, 0.3, 0.6, 1.3, 2.6, 7.7 and 17.8 mg/kg bw	0.3 mg/kg bw (LOAEL)	0.3 mg/kg bw: ↓BChE (at 5 hrs post-dosing only, **no adverse effect at 2 hrs post-dosing)** ≥0.6 mg/kg bw: ↓BChE (at 2 and at 5 hrs) ≥2.6 mg/kg bw: ↓EChE and PChE ≥7.8 mg/kg: general behavioral disturbances accompanied by muscle tremors, increased secretiion, difficult breathing and clonic convulsions
Range-finding neurotoxicity (gavage) - Wistar rats (5/sex/dose)	96.5% pure 0, 5 10 or 15 mg/kg bw in doubly distilled water		Clinical signs (dose-related) included tremors, impairment of gait, loss of pupillary reflex, irregular respiration and frequent chewing. Time of peak effect of clinical signs was 2-4 hours with 5 mg/kg be and 1-4 hours at higher doses. ↓PChE, EChE, BChE
Range-finding neurotoxicity (gavage) - Wistar rats (10 ♂/dose)	96.5% pure 0, 0.25, 0.5, 0.75 and 1.5 mg/kg bw in double distilled water		≥0.50 mg/kg bw: ↓PChE, EChE and BChE No abnormal clinical signs detected.
Acute neurotoxicity (gavage) - Wistar rats (25/sex/dose)	96.5 % pure 0, 0.2, 0.25, 0.35 and 5 mg/kg bw	LOAEL=0.2 mg/kg bw (♀) NOAEL=0.2 mg/kg bw (♂) BMDL_{10} for BChE inhibition: 0.11 - 0.17 mg/kg bw/day	≥ 0.2 mg/kg bw: ↓BChE (♀) ≥ 0.25 mg/kg bw: altered pupillary response ≥ 0.35 mg/kg bw: ↓BChE, irregular respiration (♂) 5 mg/kg bw: ↓EChE and PChE, FOB effects at 2 hrs post-dose (frequent chewing, squatting posture, no resistance to handling, anogenital staining,, tremors, gait disturbances, soft feces),↓motor activity; ↓rearing, ↓forelimb and hindlimb grip strength (♀) No neuropathology findings
4-week dietary neurotoxicity (cholinesterase assessments) - rats	0.2, 0.4, 0.8, 1.6 or 8.0 ppm (0.02, 0.04, 0.08, 0.16 or 0.8 mg/kg bw/day to young rats)	0.08 mg/kg bw/day (LOAEL) BMDL_{10} for BChE inhibition: 0.06 - 0.08 mg/kg bw/day	≥0.08 mg/kg bw/day: ↓BChE 0.16 mg/kg bw/day: ↓EChE

Study/Species/ Animal#	**Purity of A.I./ Dose Level**	**Results**	
		NOAEL (mg/kg bw/day)	**Effects**
Subchronic Toxicity - Omethoate			
3-week inhalation toxicity - Wistar rats (10/sex/dose)	92.4% pure 0, 0.00096, 0.0023 or 0.0075 mg /L in alcohol/Lutro (PEG 400) for 6 hrs/day, 5days/week	0.00096 mg/L (= 2.6 mg/kg bw/day) (LOAEL) BMCL$_{10}$ for BChE inhibition: 0.00038 - 0.00071 mg/L	0.00096 mg/L: ↓BChE (♂), ↓EChE ≥0.0023 mg/L: ↓BChE, EChE and PChE
4-week dietary toxicity - mice (50/sex/dose)	97.1% pure 0, 1, 3, or 10 ppm (≈ 0, 0.15, 0.45 or 1.5 mg/kg bw/day)	0.15 mg/kg bw/day (LOAEL)	0.15 mg/kg bw/day: ↓BChE (♂ at day 3) ≥0.45 mg/kg bw/day: ↓BChE and PChE
13-week dietary toxicity - Wistar rats (15/sex/dose)	93.3% pure 0, 0.5, 1.0, 2.0 or 4.0 ppm (≈ 0, 0.05, 0.1, 0.2 or 0.4 mg/kg bw/day)	0.05 mg/kg bw/day	≥0.1 mg/kg bw/day: ↓EChE Note: BChE not stated
13-week oral (gavage) toxicity ChE assessment - Beagle dogs (4/sex/dose)	96.6 % pure 0 or 0.0125 mg/kg bw/day in acidulated water	0.0125 mg/kg bw/day	No inhibition of PChE, EChE or BChE
Chronic Toxicity and Carcinogenicity Studies - Omethoate			
One year oral (gavage) toxicity - Beagle dogs (6/sex/dose)	97.1% pure 0, 0.025, 0.125 or 0.625 mg/kg bw/day in acidulated water	0.025/0.125 mg/kg bw/day, ♂/♀	≥0.125 mg/kg bw/day: ↓BChE and EChE (♂) 0.625 mg/kg bw/day: ↓PChE; ↓BChE and EChE (♀) Supplemental
2-year chronic dietary toxicity and carcinogenicity - mice (50/sex/dose)	94% pure 0, 1, 3, or 10 ppm (= 0/0, 0.2/0.3, 0.6/0.9 or 2.1/3.1 mg/kg bw/day, ♂/♀)	2.1/3.1 mg/kg bw/day, ♂/♀	No treatment-related effects Note: ChE not measured **NO EVIDENCE OF CARCINOGENICITY**

Study/Species/ Animal#	Purity of A.I./ Dose Level	Results	
		NOAEL (mg/kg bw/day)	Effects
2-year chronic toxicity and carcinogenicity - Wistar rats (50/sex/dose plus 10/sex/dose interim sacrifice)	96.5-97.4% pure 0, 0.5, 4 or 32 ppm in drinking water (0, 0.04/0.05, 0.30/0.44, 2.92/3.93 mg/kg bw/day, ♂/♀)	0.04 mg/kg bw/day $BMDL_{10}$ for BChE inhibition: 0.03 - 0.06 mg/kg bw/day	0.04 mg/kg bw/day: ↓EChE (♂) 0.30/0.44 mg/kg bw/day: ↓BChE; ↓EChE (♀) 2.92/3.93 mg/kg bw/day: transient ↓ weight gain, clinical signs of neurotoxicity, retinal degeneration, cataracts, corneal vascularization, forestomach lesions, ↓PChE; lens mineralization, lacrimal gland vacuolation, severe vacuolation of epididymal epithelium (♂); mammary hyperplasia (♀) **NO EVIDENCE OF CARCINOGENICITY**
Developmental and Reproductive Toxicity - Omethoate			
Developmental toxicity (gavage) - Long Evans FB rats (20-24 mated ♀/dose)	0, 0.3, 1.0 or 3.0 mg/kg bw/day on gestation days 6-15	1.0 mg/kg bw/day (maternal and developmental)	**Maternal:** 3.0 mg/kg bw/day: ↓maternal weight gain **Developmental:** 3.0 mg/kg bw/day: ↑resorption, ↓fetal weight Note: ChE activity not measured **NO EVIDENCE OF TERATOGENICITY**
Developmental toxicity (gavage) - Wistar rats (25 ♀/dose)	96.6% pure 0, 0.3, 1.0 or 3.0 mg/kg bw/day in 0.5% aqueous Crempophor on gestation days 6 - 15	1.0 mg/kg bw/day (maternal) 3.0 mg/kg bw/day (developmental)	**Maternal** 3.0 mg/kg bw/day: tremor, pale or smaller amounts of fecal pellets, ↓maternal weight gain and food consumption **Developmental** none Note: ChE activity not measured **NO EVIDENCE OF TERATOGENICITY**
Developmental toxicity (gavage) - Himalayan rabbits (15 ♀/dose + 5 ♀/dose for ChE assessements)	96.6% pure 0, 0.2, 1 or 5 mg/kg bw/day on gestation days 6-18	0.2 mg/kg bw/day (maternal LOAEL, developmental NOAEL)	**Maternal** 0.2 mg/kg bw/day: ↓BChE ≥1 mg/kg bw/day: ↓EChE 5 mg/kg bw/day: tremors, ↑heart rate, ataxia (isolated incidences), prostration, ↓weight gains (data not provided) **Developmental** ≥1 mg/kg bw/day: ↑resorption, ↑arthrogryposis (?; no dose- response relationship and historical data not available)

Study/Species/ Animal#	Purity of A.I./ Dose Level	Results	
		NOAEL (mg/kg bw/day)	Effects
Developmental toxicity (gavage) - New Zealand White rabbits (14 pregnant ♀/dose)	96.8% pure 0, 0.1, 0.3 or 1 mg/kg bw/day in distilled water on gestation days 6-18	0.3 mg/kg bw/day (maternal) 1.0 mg/kg bw/day (developmental)	1 mg/kg bw/day: ↓EChE and PChE Note: BChE not measured **NO EVIDENCE OF TERATOGENICITY**
2-generation, 1 litter/generation reproductive toxicity - Wistar rats (25/sex/dose)	0, 0.5, 3 or 18 ppm in tap water (= 0, 0.03, 0.2 or 1.2 mg/kg bw/day)	0.03 mg/kg bw/day (parental LOAEL) 0.03 mg/kg bw/day (offspring) 0.2 mg/kg bw/day (reproductive)	**Parental**: ≥0.03 mg/kg bw/day: ↓BChE and EChE 1.2 mg/kg bw/day: ↓water intake; ↓weight gain during gestation and lactation (♀), ↓food intake during lactation (♀) **Reproductive**: 1.2 mg/kg bw/day: ↓implantation rate (F1, F2), ↓pregnancy (F1), ↑implantation loss (F1), ↑pre-coital interval (F1), ↓litter size (F1, F2), ↑epithelial vacuolation in the epididymides (F1, F2) **Offspring** : ≥0.2 mg/kg bw/day: ↓BChE (F2♀) 1.2 mg/kg bw/day: ↓pup weight gain, ↑postnatal loss
Genotoxicity - Omethoate			
Reverse mutation - S. typhimurium TA98, TA100, TA1535, TA1537	95.1% pure 0-12500 µg/plate	positive:TA100 (±S9) and TA1535 (±S9) at high dose levels (>5000 µg/plate) negative: TA1537 and TA98 (±S9) up to high dose levels	
DNA repair gene mutation - E.Coli (pol) and Chinese hamster ovary cells (HGPRT)	96% pure 0-10000 µg/plate (E. Coli) 97.4% pure 0-6 mg/ml (Chinese hamster ovary cells)	Negative (E. Coli) Positive (Chinese hamster ovary cells)	
Cell mutation - L5178Y mouse lymphoma cells	96.9% pure 0 - 2000 µg/plate (-S9) 0 - 5000 µg/plate (+S9)	Equivocal Supplemental	
Sister chromatid exchange - Chinese hamster ovary cells	96% pure 0-1000 µg/plate (-S9) 0-5000 µg/plate (+S9)	Positive at ≥250 µg/plate	

Study/Species/ Animal#	Purity of A.I./ Dose Level	Results	
		NOAEL (mg/kg bw/day)	Effects
Sister chromatid exchange - in vivo - Chinese hamsters	96.7% pure 0, 5, 10 or 20 mg/kg bw in deionized water by gavage	Negative	
Micronucleus test - mouse	97.1% pure 2 × 6 or 12 mg/kg bw	Negative	
Micronucleus test - mouse	96.0% pure 0 or 22.5 mg/kg bw	Negative Clinical signs included apathy, roughened fur, prone position, spasm, palmospasm, difficulty in breathin, eyelids stuck together, lacrimation, salivation and 1/15 deaths	
Dominant lethal assay - mice	95.4% pure 0.5 mg/kg bw	Negative	
Dominant lethal assay - mice	96.6% pure 0, 10 or 20 mg/kg bw in deionized water by gavage	Negative Clinical signs included apathy, prone position, palmospasm, slitted eyes and lacrimation. 5/52 animals died at 20 mg/kg bw. Unacceptable due to lack of positive control data.	
Unscheduled DNA synthesis - in vitro - rat hepatocytes	97.4% pure 0-1030 µg/ml	Positive	
Unscheduled DNA synthesis - in vivo - Wistar rats	96.6% pure 0-30 mg/kg bw	Negative	
Spot test - C57Bl/6 x T mice	96.7-97% pure 0, 4, 8 or 16 mg/kg bw in deionised water on the 10th day of gestation	Positive ≥4 mg/kg bw: ↑ "relevant" spots 16 mg/kg bw: apathy, prone position, shivering, laboured respiration, lacrimation and salivation (time of onset and recovery were not given),	
Other Metabolites			
Acute cholinesterase assay - Sprague-Dawley rats (5♂/dose)	89.5-99.5% pure 30 mg/kg bw in distilled deionized water to all groups except Omethoate group (5 mg/kg bw)	Highest level of EChE inhibition noted with Omethoate followed by Dimethoate. The following four tested metabolites showed a markedly lower potential to inhibit cholinesterase: - O-desmethyl Omethoate (I) - O-desmethyl Omethoate carboxylic acid (II) - O-desmethyl-N-desmethyl Omethoate (III) - O-desmethyl isoDimethoate (IV) Estimated EChE inhibitory potency of Omethoate, metabolite I,II, III or IV relative to Dimethoate at 2.5 hrs (peak time of effects) = 8.4, 0.36, 0.47, 0 (no inhibition), or 0.53, respectively	

Study/Species/ Animal#	Purity of A.I./ Dose Level	Results	
		NOAEL (mg/kg bw/day)	Effects
Acute oral toxicity - rats	O-desmethyl Dimethoate	LD_{50} > 2000 mg/kg bw	

Appendix VI Occupational Exposure Risk Estimates for Dimethoate

Table 1 Dermal and Inhalation MOEs for Mixing, Loading and Applying Dimethoate with Maximum PPE and a Respirator[a]

Crop	Method of Application[b]	Rate[c] (kg a.i./ha) or (kg a.i./L)	Area Treated per day[d] (ha) or (L)	Max PPE w/respirator (open cab, open mix/load)				
				Daily Exposure (μg/kg bw/day)		Margin of Exposure (MOE)		
				Dermal[e]	Inhalation[f]	Dermal[g]	Inhalation[h]	Combined[i]
USC 4: Forests/woodlots & USC 27: Ornamentals outdoors								
birch (foliar)	airblast	0.24	16	27.53	0.04	690	2463	539
	lp handwand	2.40×10^{-4} (kg a.i./L)	150 L	0.36	2.32×10^{-3}	53266	43019	23798
	hp handwand		3750 L	23.49	0.19	809	515	315
	backpack		150 L	1.04	3.19×10^{-3}	18223	31312	1151
birch	soil injection (open pour)	0.48 (kg a.i./L)	0.3 L	0.06	$3.30 \times 10^{-}$	317501	303819	155255
	paintbrush	0.24 (kg a.i./L)	10 L	1538.51	2.55	12	39	9
boxwood	airblast	0.48	16	55.07	0.08	345	1232	270
	lp handwand	4.80×10^{-4} (kg a.i./L)	150 L	0.71	0.01	26633	21509	11899
	hp handwand		3750 L	46.98	0.39	404	258	157
	backpack		150 L	2.09	0.01	9112	15656	5760
Christmas trees (Balsam fir, hemlock, pine), pine (Mugho, Red, Scots), cedar, oak	airblast	0.96	16	110.14	0.16	173	616	135
	lp handwand	9.60×10^{-4} (kg a.i./L)	150 L	1.43	0.01	13316	10755	5950
	hp handwand		3750 L	93.97	0.78	202	129	79
	backpack		150 L	4.17	0.01	4556	7828	2880
Douglas fir seed tree	airblast	24	16	2753.39	4.06	7	25	5
	lp handwand	2.40×10^{-2} (kg a.i./L)	150 L	35.67	0.23	533	430	238
	hp handwand		3750 L	2349.17	19.41	8	5	3
	backpack		150 L	104.26	0.32	182	313	115
hemlock, spruce, Balsam fir	aerial M/L	0.72	485	145.12	0.80	131	125	64
	aerial A			35.37	0.35	537	286	187
	airblast		16	82.60	0.12	230	821	180
	lp handwand	7.20×10^{-4} (kg a.i./L)	150 L	1.07	0.01	17755	14340	7933
	hp handwand		3750 L	70.48	0.58	270	172	105
	backpack		150 L	3.13	0.01	6074	10437	3840

Crop	Method of Application[b]	Rate[c] (kg a.i./ha) or (kg a.i./L)	Area Treated per day[d] (ha) or (L)	Max PPE w/respirator (open cab, open mix/load)				
				Daily Exposure (µg/kg bw/day)		Margin of Exposure (MOE)		
				Dermal[e]	Inhalation[f]	Dermal [g]	Inhalation[h]	Combined[i]
Sitka spruce	airblast	12	16	1376.70	2.03	14	49	11
	lp handwand	1.20 × 10^{-2} (kg a.i./L)	150 L	17.84	0.12	1065	860	476
	hp handwand		3750 L	1174.58	9.71	16	10	6
	backpack		150 L	52.13	0.16	364	626	230
spruce (woodland use)	airblast	9.98	16	1145.41	1.69	17	59	13
	lp handwand	9.98 × 10^{-3} (kg a.i./L)	150 L	14.84	0.10	1280	1034	572
	hp handwand		3750 L	977.25	8.08	19	12	8
	backpack		150 L	43.37	0.13	438	753	277
USC 7: Industrial oil seed crops and fibre crops, USC 13: Terrestrial feed crops & USC 14:Terrestial food crops								
canola	aerial - M/L	0.43	400	71.81	0.40	265	253	129
	aerial - A			17.50	0.17	1086	579	377
	groundboom (c)		300	88.57	0.47	215	211	106
	groundboom (f)		100	29.52	0.16	644	633	319
flax	aerial - M/L	0.21	400	34.87	0.19	545	521	266
	aerial - A			8.50	0.08	2236	1192	777
	groundboom (c)		300	43.01	0.23	442	435	219
	groundboom (f)		100	14.34	0.08	1325	1304	657
safflower, soybeans	aerial - mix/load	0.48	400	79.79	0.44	238	228	116
	aerial - apply			19.45	0.19	977	521	340
	groundboom (c)		300	98.41	0.53	193	190	96
	groundboom (f)		100	32.81	0.18	579	570	287
USC 13: Terrestrial feed crops								
alfalfa (+ seed and forage production), clovers (sweet, red, alsike)	aerial - M/L	0.53	400	87.77	0.48	216	207	106
	aerial - A			21.39	0.21	888	473	309
	groundboom (c)		300	108.26	0.58	176	173	87
	groundboom (f)		100	36.09	0.19	527	518	261
canary seed, canary grass (seed production)	aerial - M/L	0.24	400	39.90	0.22	476	456	233
	aerial - A			9.72	0.10	1954	1042	679
	groundboom (c)		300	49.21	0.26	386	380	191
	groundboom (f)		100	16.40	0.09	1158	1139	574
forage crops (grasses, hay, clover), grains, pastures, wastelands (also USC 16)	aerial - M/L	0.48	400	79.79	0.44	238	228	116
	aerial - A			19.45	0.19	977	521	340
	r-o-w sprayer		75	248.62	0.34	76	295	61
	groundboom (c)		300	98.41	0.53	193	190	96
	groundboom (f)		100	32.81	0.18	579	570	287

Crop	Method of Application[b]	Rate[c] (kg a.i./ha) or (kg a.i./L)	Area Treated per day[d] (ha) or (L)	Max PPE w/respirator (open cab, open mix/load)				
				Daily Exposure (µg/kg bw/day)		Margin of Exposure (MOE)		
				Dermal[e]	Inhalation[f]	Dermal[g]	Inhalation[h]	Combined[i]
USC 14: Terrestrial Food Crops								
asparagus	groundboom (c)	1.10	80	60.36	0.32	315	310	156
	groundboom (f)		30	22.64	0.12	839	826	416
beans (including snap and pole)	aerial - M/L	0.48	400	79.79	0.44	238	228	116
	aerial - A			19.45	0.19	977	521	340
	groundboom (c)		300	98.41	0.53	193	190	96
	groundboom (f)		100	32.81	0.18	579	570	287
bok choi, brussel sprouts, Chinese broccoli, chicory, peppers	groundboom (c)	0.48	80	26.24	0.14	724	712	359
	groundboom (f)		30	9.84	0.05	1931	1899	957
broccoli, cauliflower	groundboom (c)	0.60	80	32.81	0.18	579	570	287
	groundboom (f)		30	12.30	0.07	1545	1519	766
cereals (barley, oats, wheat, rye) (also USC 13)	aerial - M/L	0.48	400	79.79	0.44	238	228	116
	aerial - A			19.45	0.19	977	521	340
	groundboom (c)		300	98.41	0.53	193	190	96
	groundboom (f)		100	32.81	0.18	579	570	287
leaf vegetables (beet greens, turnip greens, kale, lettuce, Swiss chard), beets, celery, eggplant	groundboom (c)	0.34	80	18.37	0.10	1034	1017	513
	groundboom (f)		30	6.89	0.04	2758	2713	1368
peas (including field and canning)	aerial - M/L	0.20	400	33.91	0.19	560	536	274
	aerial - A			8.27	0.08	2299	1225	799
	groundboom (c)		80	11.15	0.06	1703	1675	845
	groundboom (f)		30	4.18	0.02	4543	4468	2252
potatoes	groundboom (c)	0.53	300	108.26	0.58	176	173	87
	groundboom (f)		100	36.09	0.19	527	518	261
tomatoes	groundboom (c)	0.53	80	28.87	0.15	658	647	326
	groundboom (f)		30	10.83	0.06	1755	1726	870
blueberries (low and highbush)	aerial - M/L	0.40	400	66.23	0.36	287	275	140
	aerial - A			16.14	0.16	1177	628	409
	airblast		16	45.71	0.07	416	1484	325
	groundboom (c)		80	21.78	0.12	872	858	433
	groundboom (f)		30	8.17	0.04	2326	2288	1153
cherries (sweet and sour)	airblast	1.08	16	123.90	0.18	153	547	120
hazelnuts (filberts)	airblast	2.40	16	275.34	0.41	69	246	54
peaches (non-bearing)	airblast	2.16	16	247.81	0.37	77	274	60
pears	airblast	1.80	16	206.50	0.30	92	328	72
strawberries	groundboom (c)	1.32	80	72.17	0.39	263	259	131
	groundboom (f)		30	27.06	0.14	702	690	348
	chemigation		140	76.80	0.42	247	237	121

Crop	Method of Application[b]	Rate[c] (kg a.i./ha) or (kg a.i./L)	Area Treated per day[d] (ha) or (L)	Max PPE w/respirator (open cab, open mix/load)				
				Daily Exposure (µg/kg bw/day)		Margin of Exposure (MOE)		
				Dermal[e]	Inhalation[f]	Dermal[g]	Inhalation[h]	Combined[i]
USC 20: Structural								
structural	lp handwand	1.20×10^{-2} (kg a.i./L)	150 L	17.84	0.12	1065	860	476
	hp handwand		3750 L	1174.58	9.71	16	10	6
	backpack		150 L	52.13	0.16	364	626	230
USC 27: Ornamentals Outdoors								
arborvitae, juniper, taxus (yew), euonymus	airblast	0.96	16	110.14	0.16	173	616	135
	lp handwand	9.60×10^{-4} (kg a.i./L)	150 L	1.43	0.01	13316	10755	5950
	hp handwand		3750 L	93.97	0.78	202	129	79
	backapack		150 L	4.17	0.01	4556	7828	2880
azaleas, camellias, carnations, gardenias, gladioli, gerberas, poinsettas, roses	lp handwand	L)	150 L	0.71	4.65×10^{-3}	26633	21509	11899
	backpack		150 L	2.09	0.01	9112	15656	5760
roses	paintbrush	0.24 (kg a.i./L)	10 L	1538.51	2.55	12	39	9
camellias (soil drench)	lp handwand	2.88×10^{-3} (kg a.i./L)	150 L	4.28	0.03	4439	3585	1983
	backpack		150 L	12.51	0.04	1519	2609	960
carnations (soil drench)	lp handwand	6	2	118.90	0.77	160	129	71
	backpack		2	347.54	1.06	55	94	35
day lilies, irises	lp handwand	9.60×10^{-4} (kg a.i./L)	150 L	1.43	0.01	13316	10755	5950
	backpack		150 L	4.17	0.01	4556	7828	2880
holly (English, American)	airblast	0.48	16	55.07	0.08	345	1232	270
	lp handwand	4.80×10^{-4} (kg a.i./L)	150 L	0.71	4.65×10^{-3}	26633	21509	11899
	hp handwand		3750 L	46.98	0.39	404	258	157
	backapack		150 L	2.09	0.01	9112	15656	5760
larch	airblast	2.4	16	275.34	0.41	69	246	54
	lp handwand	2.40×10^{-3} (kg a.i./L)	150 L	3.57	0.02	5327	4302	2380
	hp handwand		3750 L	234.92	1.94	81	52	31
	backapack		150 L	10.43	0.03	1822	3131	1152

Crop	Method of Application[b]	Rate[c] (kg a.i./ha) or (kg a.i./L)	Area Treated per day[d] (ha) or (L)	Max PPE w/respirator (open cab, open mix/load)				
				Daily Exposure (µg/kg bw/day)		Margin of Exposure (MOE)		
				Dermal[e]	Inhalation[f]	Dermal[g]	Inhalation[h]	Combined[i]
lilac	airblast	0.6	16	68.84	0.10	276	985	216
	lp handwand	6.00 × 10^{-4} (kg a.i./L)	150 L	0.89	0.01	21306	17207	9519
	hp handwand		3750 L	58.73	0.49	324	206	126
	backapack		150 L	2.61	0.01	7289	12525	4608
	paintbrush	0.24 (kg a.i./L)	10 L	1538.51	2.55	12	39	9

[a] Mixer/Loader: an open mixing and loading system with chemical resistant coveralls over a single layer with chemical resistant gloves and a suitable respirator. Aerial Applicator: a single layer (long sleeved shirt and long pants), no gloves. All other applicators: chemical resistant coveralls over a single layer with chemical resistant gloves (no gloves for groundboom applicator). Groundboom and airblast: open cab. All products are liquid formaulations, includes solutions and emulsifiable concentrates.

[b] M/L = Mixer/Loader; A = Applicator; groundboom (c) = custom groundboom application; groundboom (f) = farmer groundboom application; LP = Low Pressure; HP = High Pressure; R-O-W = Right of Way.

[c] Maximum listed label rate in kilograms of active ingredient per hectare (kg a.i./ha) unless specified as kilograms of active ingredient per litre (kg a.i./L).

[d] Based mainly on default assumptions and stakeholder input.

[e] Where dermal exposure µg/kg/day = (unit exposure × area treated × rate)/70 kg bw, includes protection factors for additional PPE.

[f] Where inhalation exposure µg/kg/day = (unit exposure × area treated × rate)/70 kg bw; included protection factors for respirator.

[g] Based on a dermal $BMDL_{10}$ of 19 mg/kg bw/day and a target dermal MOE of 100.

[h] Based on an inhalation $BMDL_{10}$ of 0.1 mg/kg bw/day and a target inhalation MOE of 100.

[i] Calculated using the following equation: Combined MOE = 1/[1/dermal MOE + 1/inhalation MOE]. Shaded cells indicate calculated MOEs fail to meet the target MOE of 100.

Table 2 Dermal and Inhalation MOEs for Mixing, Loading and Applying Dimethoate with Additional Engineering controls[a]

Crop	Method of Application[b]	Rate[c] (kg a.i./ha) or (kg a.i./L)	Area Treated per day[d] (ha) or (L)	Additional Engineer Controls (closed cab, aerial closed mix/load)				
				Daily Exposure (µg/kg bw/day)		Margin of Exposure (MOE)		
				Dermal[e]	Inhalation[f]	Dermal[g]	Inhalation[h]	Combined[i]
USC 4: Forests/woodlots & USC 27: Ornamentals outdoors								
birch (foliar)	airblast	0.24	16	3.72	0.04	5111	2463	1662
boxwood	airblast	0.48	16	7.43	0.08	2556	1232	831
Christmas trees (Balsam fir, hemlock, pine), pine (Mugho, Red, Scots), cedar, oak	airblast	0.96	16	14.87	0.16	1278	616	416
Douglas fir seed tree	airblast	24	16	371.71	4.06	51	25	17

Crop	Method of Application[b]	Rate[c] (kg a.i./ha) or (kg a.i./L)	Area Treated per day[d] (ha) or (L)	Additional Engineer Controls (closed cab, aerial closed mix/load)				
				Daily Exposure (µg/kg bw/day)		Margin of Exposure (MOE)		
				Dermal[e]	Inhalation[f]	Dermal[g]	Inhalation[h]	Combined[i]
hemlock, spruce, Balsam fir	aerial M/L	0.72	485	47.94	0.55	396	182	125
	airblast		16	11.15	0.12	1704	821	554
Sitka spruce	airblast	12	16	185.86	2.03	102	49	33
spruce (woodland use)	airblast	9.98	16	154.63	1.69	123	59	40
USC 7: Industrial oil seed crops and fibre crops, USC 13: Terrestrial feed crops & USC 14: Terrestial food crops								
canola	aerial - M/L	0.43	400	23.72	0.27	801	368	252
	groundboom (c)		300	62.04	0.41	306	246	136
	groundboom (f)		100	20.68	0.14	919	737	409
flax	aerial - M/L	0.21	400	11.52	0.13	1649	758	520
	groundboom (c)		300	30.13	0.20	631	506	281
	groundboom (f)		100	10.04	0.07	1892	1517	842
safflower, soybeans	aerial - M/L	0.48	400	26.36	0.30	721	331	227
	groundboom (c)		300	68.94	0.45	276	221	123
	groundboom (f)		100	22.98	0.15	827	663	368
USC 13: Terrestrial feed crops								
alfalfa (+ seed and forage production), clovers (sweet, red, alsike)	aerial - M/L	0.53	400	28.99	0.33	655	301	206
	groundboom (c)		300	75.83	0.50	251	201	111
	groundboom (f)		100	25.28	0.17	752	603	334
canary seed, canary grass (seed production)	aerial - M/L	0.24	400	13.18	0.15	1442	663	454
	groundboom (c)		300	34.47	0.23	551	442	245
	groundboom (f)		100	11.49	0.08	1654	1326	736
forage crops (grasses, hay, clover), grain, pastures, wastelands (also USC 16)	aerial - M/L	0.48	400	26.36	0.30	721	331	227
	groundboom (c)		300	68.94	0.45	276	221	123
	groundboom (f)		100	22.98	0.15	827	663	368

Crop	Method of Application[b]	Rate[c] (kg a.i./ha) or (kg a.i./L)	Area Treated per day[d] (ha) or (L)	Additional Engineer Controls (closed cab, aerial closed mix/load)				
				Daily Exposure (µg/kg bw/day)		Margin of Exposure (MOE)		
				Dermal[e]	Inhalation[f]	Dermal[g]	Inhalation[h]	Combined[i]
USC 14: Terrestrial Food Crops								
asparagus	groundboom (c)	1.10	80	42.28	0.28	449	360	200
	groundboom (f)		30	15.86	0.10	1198	961	533
beans (including snap and pole)	aerial - M/L	0.48	400	26.36	0.30	721	331	227
	groundboom (c)		300	68.94	0.45	276	221	123
	groundboom (f)		100	22.98	0.15	827	663	368
bok choi, brussel sprouts, Chinese broccoli, chicory, peppers	groundboom (c)	0.48	80	18.38	0.12	1034	829	460
	groundboom (f)		30	6.89	0.05	2756	2210	1226
broccoli, cauliflower	groundboom (c)	0.60	80	22.98	0.15	827	663	368
	groundboom (f)		30	8.62	0.06	2205	1768	981
cereals (barley, oats, wheat, rye) (also USC 13)	aerial - M/L	0.48	400	26.36	0.31	721	331	227
	groundboom (c)		300	68.94	0.45	276	221	123
	groundboom (f)		100	22.98	0.15	827	663	368
leaf vegetables (beet greens, turnip greens, kale, lettuce, Swiss chard), beets, celery, eggplant	groundboom (c)	0.34	80	12.87	0.08	1477	1184	657
	groundboom (f)		30	4.83	0.03	3937	3157	1752
peas (including field and canning)	aerial - M/L	0.20	400	11.20	0.13	1696	780	534
	groundboom (c)		80	7.81	0.05	2432	1950	1082
	groundboom (f)		30	2.93	0.02	6485	5199	2886
potatoes	groundboom (c)	0.53	300	75.83	0.50	251	201	111
	groundboom (f)		100	25.28	0.17	752	603	334
tomatoes	groundboom (c)	0.53	80	20.22	0.13	940	753	418
	groundboom (f)		30	7.58	0.05	2506	2009	1115
blueberries (low and highbush)	aerial - M/L	0.40	400	21.88	0.25	868	399	274
	airblast		16	6.17	0.07	3079	1484	1001
	groundboom (c)		80	15.26	0.10	1245	998	554
	groundboom (f)		30	5.72	0.04	3321	2662	1478

Crop	Method of Application[b]	Rate[c] (kg a.i./ha) or (kg a.i./L)	Area Treated per day[d] (ha) or (L)	Additional Engineer Controls (closed cab, aerial closed mix/load)				
				Daily Exposure (µg/kg bw/day)		Margin of Exposure (MOE)		
				Dermal[e]	Inhalation[f]	Dermal[g]	Inhalation[h]	Combined[i]
cherries (sweet and sour)	airblast	1.08	16	16.73	0.18	1136	547	369
hazelnuts (filberts)	airblast	2.40	16	37.17	0.41	511	246	166
peaches (non-bearing)	airblast	2.16	16	33.45	0.37	568	274	185
pears	airblast	1.80	16	27.88	0.30	682	328	222
strawberries	groundboom (c)	1.32	80	50.55	0.33	376	301	167
	groundboom (f)		30	18.96	0.12	1002	803	446
USC 27: Ornamentals Outdoors								
arborvitae, juniper, taxus (yew), euonymus	airblast	0.96	16	14.87	0.16	1278	616	416
holly (English, American)	airblast	0.48	16	7.43	0.08	2556	1232	831
larch	airblast	2.40	16	37.17	0.41	511	246	166
lilac	airblast	0.60	16	9.29	0.10	2045	985	665

[a] Mixer/Loader (aerial): a closed mixing and loading system with maximum PPE. Mixer/Loader (all other): an open mixing and loading system with chemical resistant coveralls over a single layer with chemical resistant gloves and a suitable respirator. Groundboom and airblast applicators: closed cab with cotton coveralls over a single layer, with gloves for airblast (no gloves for groundboom). All products are liquid formulations, includes solutions and emulsifiable concentrates.

[b] M/L = Mixer/Loader; groundboom (c) = custom groundboom application; groundboom (f) = farmer groundboom application.

[c] Maximum listed label rate in kilograms of active ingredient per hectare (kg a.i./ha) unless specified as kilograms of active ingredient per litre (kg a.i./L).

[d] Based mainly on default assumptions and stakeholder input.

[e] Where dermal exposure µg/kg/day = (unit exposure × area treated × rate)/70 kg bw, includes protection factors for additional PPE.

[f] Where inhalation exposure µg/kg/day = (unit exposure × area treated × rate)/70 kg bw; included protection factors for respirator.

[g] Based on a dermal $BMDL_{10}$ of 19 mg/kg bw/day and a target dermal MOE of 100.

[h] Based on an inhalation $BMDL_{10}$ of 0.1 mg/kg bw/day and a target inhalation MOE of 100.

[i] Calculated using the following equation: Combined MOE = 1/[1/dermal MOE + 1/inhalation MOE]. Shaded cells indicate calculated MOEs fail to meet the target MOE of 100.

Table 3 Dermal and Inhalation MOEs for Mixing, Loading and Applying with Open Cab Airblast with Additional PPE[a]

USC[b]	Crop	Method of Application	Rate[c] (kg a.i./ha)	Area Treated[d] (ha/day)	Daily Exposure (µg/kg/day)		Margin of Exposure		
					Dermal[e]	Inhalation[f]	Dermal[g]	Inhalation[h]	Combined[i]
4 & 27	spruce (woodland use)	airblast	9.98	16	205.59	1.69	92	59	36
4 & 27	birch (foliar)	airblast	0.24	16	4.94	0.04	3845	2463	1501
4 & 27	boxwood	airblast	0.48	16	9.88	0.08	1922	1232	751
4 & 27	Christmas trees (Balsam fir, spruce, hemlock, pine), pine (Mugho, Red, Scots), cedar, oak	airblast	0.96	16	19.77	0.16	961	616	375
4 & 27	Doulgas fir seed tree	airblast	24.00	16	494.20	4.06	38	25	15
4 & 27	hemlock, spruce, Balsam fir	airblast	0.72	16	14.83	0.12	1282	821	500
4 & 27	Sitka spruce	airblast	12.00	16	247.10	2.03	77	49	30
14	blueberry (highbush)	airblast	0.40	16	8.20	0.07	2316	1484	904
14	cherries (sweet and sour)	airblast	1.08	16	22.24	0.18	854	547	334
14	hazelnuts (filberts)	airblast	2.40	16	49.42	0.41	384	246	150
14	peaches (non-bearing)	airblast	2.16	16	44.48	0.37	427	274	167
14	pears	airblast	1.80	16	37.07	0.30	513	328	200
27	arborvitae, juniper, taxus (yew), euonymus	airblast	0.96	16	19.77	0.16	961	616	375
27	holly	airblast	0.48	16	9.88	0.08	1922	1232	751

USC[b]	Crop	Method of Application	Rate[c] (kg a.i./ha)	Area Treated[d] (ha/day)	Daily Exposure (µg/kg/day)		Margin of Exposure		
					Dermal[e]	Inhalation[f]	Dermal[g]	Inhalation[h]	Combined[i]
27	larch	airblast	2.40	16	49.42	0.41	384	246	150
27	lilac	airblast	0.60	16	12.36	0.10	1538	985	601

[a] Mixer/Loader: an open mixing and loading system with chemical resistant coveralls over a single layer , chemical resistant gloves and a suitable respirator. Airblast applicators: open cab with chemical resistant coveralls over a single layer, chemical resistant gloves, chemical resistant headgear and a suitable respirator. All products are liquid formulations, includes solutions and emulsifiable concentrates.

[b] USC = Use Site Category; USC 4 = forests and woodlots; USC 14 = terrestrial food crops; USC 27 = ornamentals outdoors.

[c] Maximum listed label rate in kilograms of active ingredient per hectare (kg a.i./ha).

[d] Based on default assumption.

[e] Where dermal exposure µg/kg/day = (unit exposure × area treated × rate)/70 kg bw; includes protection factors for additional PPE.

[f] Where inhalation exposure µg/kg/day = (unit exposure × area treated × rate)/70 kg bw; included protection factors for respirator.

[g] Based on a dermal BMDL_{10} of 19 mg/kg bw/day and a target dermal MOE of 100.[h] Based on an inhalation BMDL_{10} of 0.1 mg/kg bw/day and a target inhalation MOE of 100.

[i] Calculated using the following equation: Combined MOE = 1/[1/dermal MOE + 1/inhalation MOE]. Shaded cells indicate calculated MOEs fail to meet the target MOE of 100.

Table 4 Postapplication Exposure Estimates, MOEs and REIs for Dimethoate

Crop	Rate[a] (kg a.i./ha)	Applications		Activity	Transfer Coefficient[d] (cm^2/hr)	DFR[e] (µg/cm^2)	Dermal Exposure[f] (µg/kg bw/day)	MOE[g]	REI[h] (days)
		Number[b]	Interval[c] (days)						
USC 4: Forests and woodlots & USC 27: Ornamentals outdoors									
birch (foliar)	0.24	2	10	thinning	3000	0.45	152.58	125	0.5
				hand-line irrigation	1100	0.45	55.95	340	0.5
				hand pruning, scouting, pinching, tying, training	500	0.45	25.43	747	0.5
				hand weeding, propping, animal control, baiting, grading	100	0.45	5.09	3736	0.5

Crop	Rate[a] (kg a.i./ha)	Applications		Activity	Transfer Coefficient[d] (cm^2/hr)	DFR[e] (µg/cm^2)	Dermal Exposure[f] (µg/kg bw/day)	MOE[g]	REI[h] (days)
		Number[b]	Interval[c] (days)						
boxwood	0.48	2	10	thinning	3000	0.55	187.66	101	7
				hand-line irrigation	1100	0.89	111.89	170	0.5
				hand pruning, scouting, pinching, tying, training	500	0.89	50.86	374	0.5
				hand weeding, propping, animal control, baiting, grading	100	0.89	10.17	1868	0.5
cedar, oak, Christmas trees (Balsam fir, spruce, hemlock, pine), pine (Mugho, Red, Scots)	0.96	2	10	thinning	3000	0.53	182.18	104	18
				hand-line irrigation	1100	1.44	181.32	105	3
				hand pruning, scouting, pinching, tying, training, shaping	500	1.78	101.72	187	0.5
				hand weeding, propping, animal control, baiting, grading, tagging	100	1.78	20.34	934	0.5
Douglas fir seed tree	24.00	2	10	Seed cone harvesting	3000	0.55	189.42	100	105
				hand-line irrigation	1100	1.47	184.79	103	66
				hand pruning, scouting, pinching, tying, training	500	3.27	187.11	102	44
				hand weeding, propping, animal control, baiting, grading	100	16.08	183.79	103	15
hemlock, spruce, balsam fir	0.72	2	10	thinning	3000	0.55	188.39	101	13
				hand-line irrigation	1100	1.34	167.84	113	0.5
				hand pruning, scouting, pinching, tying, training	500	1.34	76.29	249	0.5
				hand weeding, propping, animal control, baiting, grading	100	1.34	15.26	1245	0.5

Crop	Rate[a] (kg a.i./ha)	Applications		Activity	Transfer Coefficient[d] (cm^2/hr)	DFR[e] (µg/cm^2)	Dermal Exposure[f] (µg/kg bw/day)	MOE[g]	REI[h] (days)
		Number[b]	Interval[c] (days)						
Sitka spruce	12.00	2	10	thinning	3000	0.54	185.47	102	77
				hand-line irrigation	1100	1.50	188.79	101	46
				hand pruning, scouting, pinching, tying, training	500	3.27	186.89	102	30
				hand weeding, propping, animal control, baiting, grading	100	15.70	179.37	106	5
spruce (woodland use)	9.98	2	10	thinning	3000	0.54	186.56	102	70
				hand-line irrigation	1100	1.49	187.27	101	25
				hand pruning, scouting, pinching, tying, training	500	3.22	183.92	103	27
				hand weeding, propping, animal control, baiting, grading	100	16.08	183.83	103	2
USC 7: Industrial oil seed crops and fibre crops, USC 13: Terrestrial feed crops & USC 14: Terrestrial food crops									
canola	0.43	2	7	scouting	1500	0.55	94.25	202	0.5
flax	0.21	2	7	scouting	1500	0.27	45.77	415	0.5
soybeans, safflower	0.48	2	7	scouting, irrigation	1500	0.61	104.73	181	0.5
				hand weeding	100	0.61	6.98	2721	0.5
USC 13: Terrestrial feed crops									
alfalfa, sweet clover, red clover, alsike clover	0.53	2	7	scouting, irrigation	1500	0.67	115.20	165	0.5
canary seed and grass[d]	0.24	2	7	scouting, irrigation	1500	0.31	52.36	363	0.5
forage crops, grains, pastures and wastelands (also USC 16)	0.48	2	7	scouting, irrigation	1500	0.61	104.73	181	0.5

Crop	Rate[a] (kg a.i./ha)	Applications		Activity	Transfer Coefficient[d] (cm^2/hr)	DFR[e] (µg/cm^2)	Dermal Exposure[f] (µg/kg bw/day)	MOE[g]	REI[h] (days)
		Number[b]	Interval[c] (days)						
USC 14: Terrestrial food crops									
asparagus [d]	1.10	2	7	hand harvesting, transplanting	1000	1.41	160.58	118	0.5
				scouting, irrigation	500	1.41	80.29	237	0.5
				hand weeding	300	1.41	48.17	394	0.5
beans	0.48	2	7	hand harvesting	2500	0.61	174.55	109	0.5
				scouting, irrigation	1500	0.61	104.73	181	0.5
				hand weeding, thinning	100	0.61	6.98	2721	0.5
broccoli, cauliflower	0.60	2	7	hand harvesting, irrigating, hand pruning	5000	0.30	174.23	109	5
				scouting	4000	0.23	104.86	181	2
				hand weeding, thinning	2000	0.76	174.55	109	0
cereals (barley, oats, wheat, rye) (also USC 13)	0.48	2	7	scouting, irrigation	1500	0.61	104.73	181	0.5
bok choi, chicory, Chinese broccoli	0.48	2	7	hand harvesting, thinning	2500	0.65	184.31	103	4
				scouting, irrigation	1500	0.96	164.80	115	2
				hand weeding	500	1.53	87.37	217	0.5
brussel sprouts	0.48	2	7	hand harvesting, irrigation, topping	5000	0.18	104.86	181	2
				scouting	4000	0.18	83.88	227	2
				hand weeding	2000	0.61	139.64	136	0.5
eggplant	0.34	2	7	hand harvesting, hand pruning, staking, tying	1000	0.43	48.87	389	0.5
				scouting, irrigation	700	0.43	34.21	555	0.5
				hand weeding, thinning	500	0.43	24.44	778	0.5

Crop	Rate[a] (kg a.i./ha)	Applications		Activity	Transfer Coefficient[d] (cm^2/hr)	DFR[e] (µg/cm^2)	Dermal Exposure[f] (µg/kg bw/day)	MOE[g]	REI[h] (days)
		Number[b]	Interval[c] (days)						
leaf vegetables: beets (beet greens), turnip greens, kale, lettuce, Swiss chard, celery	0.34	2	7	hand harvesting, thinning	2500	0.55	156.26	122	3
				scouting, irrigation	1500	1.07	183.48	104	0.5
				hand weeding	500	1.07	61.16	311	0.5
peas	0.20	2	7	hand harvest	2500	0.26	74.18	256	0.5
				scouting, irrigation	1500	0.26	44.51	427	0.5
				hand weeding	100	0.26	2.97	6403	0.5
peppers	0.48	2	7	hand harvesting, hand pruning, staking, tying	1000	0.61	69.82	272	0.5
				scouting, irrigation	700	0.61	48.87	389	0.5
				hand weeding	500	0.61	34.91	544	0.5
potatoes	0.53	2	7	scouting, irrigation	1500	0.67	115.20	165	0.5
				hand weeding	300	0.67	23.04	825	0.5
tomatoes	0.53	2	7	hand harvesting, hand pruning, staking, tying, thinning	1000	0.67	76.80	247	0.5
				scouting, irrigation	700	0.67	53.76	353	0.5
				hand weeding	500	0.67	38.40	495	0.5
blueberries (highbush)	0.40	2	10	hand harvest, hand pruning, thinning	5000	0.32	185.56	102	12
				scouting	1000	0.74	84.43	225	0.5
				hedging, irrigating, hand weeding	500	0.74	42.21	450	0.5
blueberries (lowbush)	0.40	2	10	hand harvest, hand pruning	1500	0.74	126.64	150	0.5
				thinning, scouting, irrigating, hand weeding	400	0.74	33.77	563	0.5

Crop	Rate[a] (kg a.i./ha)	Applications		Activity	Transfer Coefficient[d] (cm^2/hr)	DFR[e] (µg/cm^2)	Dermal Exposure[f] (µg/kg bw/day)	MOE[g]	REI[h] (days)
		Number[b]	Interval[c] (days)						
cherries	1.08	2	10	thinning	3000	0.53	180.94	105	20
				hand harvesting	1500	1.08	184.35	103	9
				hand-line irrigation	1100	1.41	177.58	107	5
				hand pruning, scouting, pinching, tying, training	500	2.00	114.43	166	0.5
				mechanical harvesting	200	2.00	45.77	415	0.5
				hand weeding, propping, animal control, baiting, grading	100	2.00	22.89	830	0.5
hazelnuts (filberts)	2.40	2	10	thinning	3000	0.53	181.19	105	34
				hand harvesting	1500	1.10	189.08	100	21
				hand-line irrigation	1100	1.51	189.59	100	16
				hand pruning, scouting, pinching, tying, training	500	3.14	179.37	106	5
				mechanical harvesting	200	4.45	101.72	187	0.5
				hand weeding, propping, animal control, baiting, grading	100	4.45	50.86	374	0.5
peaches (non-bearing)	2.16	2	10	thinning	3000	0.53	181.15	105	32
				hand-line irrigation	1100	1.45	181.95	104	15
				hand pruning, scouting, pinching, tying, training	500	3.25	185.44	102	3
				hand weeding, propping, animal control, baiting, grading	100	4.01	45.77	415	0.5

Crop	Rate[a] (kg a.i./ha)	Applications		Activity	Transfer Coefficient[d] (cm^2/hr)	DFR[e] (µg/cm^2)	Dermal Exposure[f] (µg/kg bw/day)	MOE[g]	REI[h] (days)
		Number[b]	Interval[c] (days)						
pears	1.80	2	10	thinning	3000	0.55	187.98	101	28
				hand harvesting	1500	1.06	181.93	104	17
				hand-line irrigation	1100	1.47	184.44	103	12
				hand pruning, scouting, pinching, tying, training	500	3.11	177.75	107	1
				hand weeding, propping, animal control, baiting, grading	100	3.34	38.14	498	0.5
strawberries	1.32	2	7	hand harvesting, pinching, hand pruning, training	1500	0.50	86.51	220	2
				scouting, irrigation, mulching, hand weeding	400	1.68	76.80	247	0.5
USC 27: Ornamentals outdoors									
arborvitae, juniper, taxus (yew), euonymus	0.96	2	10	all activities	400	1.78	81.37	233	0.5
azaleas, camellias, carnations, gerberas, gladioli, poinsettias, roses	0.48	2	7	all activities	4000	0.18	83.88	227	2
day lilies, irises	0.96	2	7	all activities	4000	0.38	175.44	108	7
holly	0.48	2	10	all activities	4000	0.39	178.85	106	12

Crop	Rate[a] (kg a.i./ha)	Applications		Activity	Transfer Coefficient[d] (cm^2/hr)	DFR[e] (µg/cm^2)	Dermal Exposure[f] (µg/kg bw/day)	MOE[g]	REI[h] (days)
		Number[b]	Interval[c] (days)						
larch	2.40	2	10	all activities	400	4.15	189.60	100	1
lilac	0.60	2	10	all activities	4000	0.40	183.79	103	15

[a] Maximum listed label rates expressed in kilograms a.i./hectare.

[b] All crops were assessed using a maximum of 2 applications per year as per the available DFR data.

[c] A seven or ten day interval was applied to all crops based on the available DFR data.

[d] Transfer coefficients are from the Science Advisory Council for Exposure Agricultural Transfer Coefficient document and any amendments thereof. The artichoke TC for hand harvesting was used as a surrogate to estimate exposure for hand harvesting asparagus. Forage crop TCs were used to estimate exposure for canary seed and grass.

[e] Estimated Dislodgeable Foliar Residue (DFR) is based on DFR data, at × days after application, where × is the day when an MOE ≥100 is determined for the proposed REI (restricted-entry interval).

[f] Dermal exposure = DFR × TC × 8 hr / 70 kg.

[g] The resulting MOE on the recommended REI day. Based on the short and intermediate term dermal BMDL$_{10}$ of 19 mg/kg bw/day.

[h] Day at which the dermal exposure results in an MOE ≥100. Where target MOE was met on Day 0, minimum REI of 0.5 days (12 hrs) was recommended.

Appendix VII Aggregate Acute and Short-Term Exposure and Risk Assessment

Table 1 Aggregate Exposure for PYO Operations

Crop	Subject [a]	Application Rate (kg a.i./ha) [b]	Activity	Dermal MOE [c]	Dietary MOE [d]	Combined MOE [e]
strawberries	adult	1.32	hand harvest	826	3368	663
	youth			669	2121	509
	toddler			415	1149	305
cherries	adult	1.08	hand harvest	878	5439	755
	youth			711	4262	609
	toddler			442	1129	318
pears	adult	1.8	hand harvest	410	5439	381
	youth			333	353	171
	toddler			206	298	122

[a] Three different age groups were assessed for PYO exposure. The body weights are as follows: 15 kg for toddlers, 39.1 kg for youth, and 70 kg for adults.

[b] Maximum listed label rates expressed in kilograms a.i/hectare.

[c] Based on the short- and intermediate-term dermal BMDL$_{10}$ of 19 mg/kg/day and a dermal target MOE of 100.

[d] Based on the acute oral endpoint of 1.3 mg/kg/day and a dietary target MOE of 100.

[e] Calculated using the following equation: Combined MOE = 1 / [1/dermal MOE + 1/dietary MOE]. If the calculated MOEs exceeds 100, the risk is below the level of concern.

Appendix VIII Dietary Exposure and Risk Estimates for Dimethoate

Table 1 Acute Dietary Exposure and Risk Estimates for Dimethoate

Population Groups	Exposure from Food[1]		Exposure from Food and Water[1]			
			Water Estimates based on Modelled EECs		Water Estimates based on Monitoring Data	
	(mg/kg bw/day)	% ARfD[2]	(mg/kg bw/day)	%ARfD[2]	(mg/kg bw/day)	% ARfD[2]
General Population	0.004783	37	0.015363	117	0.007215	56
All Infants (<1 years)	0.005148	40	0.052992	408	0.014057	108
Children 1-2 years	0.008712	67	0.023382	180	0.010039	77
Children 3-5 years	0.008022	62	0.021992	169	0.010529	81
Children 6-12 years	0.0073	56	0.016063	124	0.008361	64
Males 13-19 years	0.004714	36	0.011785	91	0.007755	60
Males 20-49 years	0.003479	27	0.013767	106	0.005172	40
Adults 50+ years	0.002756	21	0.013086	101	0.004193	32
Females 13-49 years	0.003842	30	0.013839	106	0.005665	44

EEC = estimated environmental concentration, ARfD = acute reference dose

Acute exposure reported at the 99.9th percentile of exposure

[1] Exposure accounts for both Dimethoate and Omethoate residues. 12x acute toxicological adjustment factor (TAF) was applied to Omethoate residue estimates.

[2] Acute Reference Dose = 0.013 mg/kg bw/day

Table 2 Chronic Dietary Exposure and Risk Estimates for Dimethoate

Population Groups	Exposure from Food[1]		Exposure from Food and Water[1] Water Estimates based on Modelled EECs	
	(mg/kg bw/day)	% ADI[2]	(mg/kg bw/day)	% ADI[2]
General Population	0.000114	6	0.000272	14
All Infants (<1 years)	0.000162	8	0.00068	34
Children 1-2 years	0.00027	14	0.000505	25
Children 3-5 years	0.000251	13	0.000471	24
Children 6-12 years	0.000171	9	0.000323	16
Males 13-19 years	0.000109	5	0.000223	11
Males 20-49 years	0.000095	5	0.000242	12
Adults 50+ years	0.000081	4	0.000236	12
Females 13-49 years	0.000091	5	0.000238	12

EEC = estimated environmental concentration, ADI = Acceptable Daily Intake

[1] Exposure accounts for both Dimethoate and Omethoate residues. 3x chronic toxicological adjustment factor (TAF) was applied to Omethoate residue estimates.

[2] ADI = 0.002 mg/kg bw/day

Appendix IX Food Residue Chemistry Summary

1.0 Metabolism

1.1 Livestock metabolism

Limited livestock metabolism data was available on file with the PMRA. However, based on foreign reviews from USEPA (2002b) and Joint Food and Agricultural Organization/World Health Organization Meeting of Pesticide Residues (JMPR) it can be concluded that the residues to be regulated in animal matrices are Dimethoate and Omethoate.

In the rat, the principal pathway for the metabolism of Dimethoate involves cleavage of the C-N bond to yield Dimethoate carboxylic acid that is subsequently metabolized to dimethyl dithiophosphate, dimethyl thiophosphoric acid and dimethyl phosphoric acid. A minor metabolic pathway involves oxidation of Dimethoate to its oxygen analog, Omethoate, that is subsequently metabolized to dimethyl thiophosphoric acid and dimethyl phosphoric acid. Loss of the methoxy groups of the parent to yield carbon dioxide is another minor metabolic pathway

In poultry and ruminants, the principal metabolic pathway involves conversion of Dimethoate to its oxygen analog, Omethoate, and cleavage of the phosphorus-sulfur bond, resulting in the phosphorylation of natural products. The data indicates that the only metabolites which are likely to incur in meat, milk, poultry, and eggs are residues of Omethoate (found in liver and egg white samples) and Dimethoate carboxylic acid (found in liver, egg whites, and milk samples). No detectable residues of Dimethoate were found in liver, kidney, fat, muscle, milk, and egg samples from any of the available ruminant and poultry metabolism and feeding studies.

For confirmatory purposes, the registrant is requested to submit the relevant animal metabolism studies that were submitted to USEPA and JMPR. Additional metabolism data is required to characterize residues in milk.

1.2 Plant metabolism

Limited plant metabolism data were available on file with the PMRA. However, based on foreign reviews from USEPA, JMPR, and European Food Safety Authority (EFSA) it can be concluded that the residues to be regulated are Dimethoate and Omethoate.

The USEPA concluded that the qualitative nature of the residue in plants is adequately understood. Dimethoate is readily taken up by roots or leaf surfaces, and translocated throughout treated plants. It is rapidly metabolized in plants by competing hydrolytic and oxidative processes. Similar conclusions were made by JMPR and EFSA.

Oxidative desulfuration converts Dimethoate to its oxygen analog, Omethoate, a potent cholinesterase inhibitor. Available residue chemistry data suggested that under favourable conditions levels of Omethoate may exceed levels of Dimethoate. This potential was evidenced by available USDA PDP monitoring data.

Oxidative N-demethylation of Dimethoate or Omethoate results in the formation of N-hydroxymethylated and N-demethylated derivatives of Dimethoate and Omethoate which are potent cholinesterase inhibitors. Conjugates of N-hydroxymethylated derivatives of Dimethoate and Omethoate are also formed. Levels of these metabolites are expected to be low compared to levels of Dimethoate and/or Omethoate but may, under favorable conditions, reach levels of significance.

Hydrolysis of amide or phosphate ester bonds of Dimethoate and its potent cholinesterase inhibiting metabolites discussed above results in the formation of O-demethylated, carboxylated (cleavage of the C-N bond), and O-demethylated/carboxylated derivatives which are likely less potent cholinesterase inhibitors. O-desmethyl Dimethoate and Dimethoate carboxylic acid have been identified as major plant metabolites. The residues to be regulated in plants are Dimethoate and its oxidative analog, Omethoate.

Roberts and Hutson (1999) summarized the degradation of Dimethoate in cherries, peaches, grapes, sugar beet, wheat and sorghum. The principle route of metabolism was via oxidation to Omethoate. O-Demethylation of Dimethoate also led to the formation of des-O-methylDimethoate as a major catabolic route. Hydrolysis of the amide function of Dimethoate, Omethoate, and des-O-methylDimethoate gave rise to Dimethoate carboxylic acid, Omethoate carboxylic acid, and des-O-methylDimethoate carboxylic acid.

Potato metabolism data indicated that Omethoate and O-desmethyl N-desmethyl Omethoate were the most significant metabolites. Dimethoate carboxylic acid, dimethyl dithiophosphate, O-desmethyl isoDimethoate, O-desmethyl Omethoate, and O-desmethyl Omethoate carboxylic acid were identified as minor metabolites. Omethoate, O-desmethyl N-desmethyl Omethoate, and O-desmethyl isoDimethoate were identified as the major metabolites in wheat. Dimethyl dithiophosphate and O-desmethyl Omethoate carboxylic acid were identified as minor metabolites. For confirmatory purposes, the PMRA requests the registrant to submit the relevant potato and wheat metabolism studies.

2.0 Residue Definition

The existing metabolism data supports that current residue definition in plant and animal matrices, which includes Dimethoate and the oxon metabolite, Omethoate.

The USEPA has established the same definition. JMPR concluded that the residue for compliance with MRLs should be defined as Dimethoate. In addition, the JMPR has recommended that MRLs for Omethoate be withdrawn because of a lack of residue data for commodities treated with Omethoate. For the purposes of carrying out dietary risk assessments, JMPR considers the sum of Dimethoate and Omethoate as do the PMRA and the USEPA.

Several transformation products were identified in plants and animal metabolism data in addition to Omethoate. Three of these metabolites were detected at significant amounts in plants and were identified as potential cholinesterase inhibitors; O-desmethyl Omethoate, O-desmethyl Omethoate carboxylic acid, and O-desmethyl isoDimethoate. Dimethoate carboxylic acid was identified as a significant metabolite in animal matrices. Limited toxicology data indicates that the plant metabolites are less potent cholinesterase inhibitors compared to the parent. There is no data to characterize the toxicology of Dimethoate carboxylic acid. Overall, there is a lack of data to determine the exposure and toxicology of these compounds, thus additional food residue and toxicology studies are required in order to quantitatively determine their risk contribution.

3.0 Analytical Methods

3.1 Methods for Residue Analysis of Plants and Plant Products

The USEPA (1999) reports that adequate methods are available for data collection and tolerance enforcement The Pesticide Analytical Manual (PAM) Volume II lists three gas chromatography (GC) methods using flame photometric detection (FPD) for analysis of residues of Dimethoate and Omethoate in/on plant and animal commodities. The limits of detection (LOD) ranged from 0.001 ppm in milk to 0.05 ppm in forage/straw.

JMPR (2003) and EFSA (2006) reviews describe methods similar to those referred to in the American assessment. Maceration/extraction of the substrate was with acetone/water, and extraction of the concentrated extract with chloroform or methylene chloride. Final extracts were analysed with GC-FPD. The LOD was reported to be 0.01 ppm for the parent and Omethoate. Both JMPR and EFSA stated that adequate methods exist for data collection, monitoring and for the enforcement of MRLs.

Limited plant analytical methodology data is available on file with PMRA. For confirmatory purposes, the registrant is requested to submit analytical methodology data to the PMRA.

3.2 Methods for residue analysis in food of animal origin

The USEPA (2002d) refers to the method used for plants matrices as the analytical method of Dimethoate and Omethoate residues in food of animal origin. Radiovalidation data for livestock studies remain outstanding and are considered confirmatory.

JMPR also refers to the GC-FPD method used for plant matrices. LOQs were 0.001 ppm for milk and eggs and 0.01 ppm for tissues.

No animal analytical methodology data is available on file with PMRA. For confirmatory purposes, the registrant is requested to submit analytical methodology data to the PMRA.

3.3 Multi-residue method

According to the USEPA (2002d), the USFDA PESTDATA database from 1994 (PAM Volume I, Appendix I) indicates that Dimethoate and Omethoate are completely recovered (>80%) using Multi-residue method Section 302 (Luke method; Protocol D).

USDA PDP and CFIA residue surveillance programs contain suitable multi residue method for analysing Dimethoate and Omethoate. The LODs for methods utilized by CFIA are 0.017 and 0.034 ppm for Dimethoate and Omethoate , respectively. PDP analytical method LODs are specific to individual crops and hence varies depending on the commodity sampled. In general LODs from PDP analytical methods are lower than those from CFIA.

4.0 Storage Stability

The USEPA report that storage stability data had been submitted for cottonseed (oil seeds), oranges (fruits/fruiting vegetables), potatoes (root crops), sorghum grain (non oily grains), and sorghum forage (leafy vegetables). The data demonstrated that spiked residues of Dimethoate and Omethoate in these commodities were stable under frozen conditions for approximately 27 months. Other data reviewed by the USEPA indicated that Dimethoate residues were stable for up to 12 months in lettuce and for up to 6 months in/on apples. As storage stability data was provided for 5 dissimilar crops, it is adequate to satisfy the data requirements for all plant commodities.

No storage stability data was submitted for processed commodities. The USEPA assessment indicated that data were not required for citrus, field corn, cottonseed, grape, potato, tomato and wheat processing studies because of the stability of residues in the raw agricultural commodity (RAC) and because of the relatively short frozen storage intervals of test samples from these processing studies.

JMPR reviewed the same storage stability data for cottonseed, oranges, potatoes, sorghum grain and sorghum forage in 1998 and came to the conclusion that Dimethoate and Omethoate residues were stable for at least 1.7 years. There was also data in their more recent evaluation (2003) which indicated that Dimethoate and Omethoate residues are stable in cherries for up to 6 months at -18°C. However, residues of both compounds slightly declined in mangos that were stored for 3 months in -18°C.

EFSA (2006) indicated that Dimethoate and Omethoate residues are stable for up to 27 months in potato, orange fruit, sorghum grain/forage and cottonseed as well as cherries stored for 6 months when frozen between -10°C and -20°C.

Based on the above, it can be concluded that residues will be stable for a minimum of one year in vegetables and citrus and 6 months for fruits other than citrus. Additional storage stability data is required for Dimethoate and Omethoate residues in animal matrices.

There are no storage stability data on file with the PMRA. For confirmatory purposes, the registrant is requested to submit any relevant plant storage stability data that was submitted to the other regulatory agencies.

The American assessment indicated that storage stability data are necessary for meat, milk, poultry and eggs. The registrant is requested to submit storage stability data for animal matrices to the PMRA in accordance with the requirements specified in Regulatory Directive, DIR98-02, *Residue Chemistry Guidelines*.

5.0 Magnitude of Residue

There are insufficient magnitude of residue data available. The studies on file are inadequate for one or more of the following reasons: inappropriate or undefined crop zones used, inadequate number of trials conducted, the residues measured (parent only), rate/# of applications/PHI used (not at current GAP), or because data was insufficiently detailed to determine these critical factors. Field trial studies are required to verify or establish MRLs for asparagus, barley, beans, beets, blueberry, broccoli, brussel sprouts, canola, cauliflower, chicory, flax, lettuce, peas, pears, peppers, potato, safflower, Swiss chard, soybean, strawberry, tomato, and turnips . These studies should be conducted in Canadian regions and in accordance with Canadian GAP. Additional field trial studies for the following imported commodities are required in order to establish or confirm import MRLs; artichoke, corn, cotton, endives, citrus, guava, lentils, mango, melons (cantaloupe, casaba, honeydew, watermelon), mustard greens, olives, pecan, starfruit, sorghum, and sugar beets.

6.0 Crop Rotation

No information on crop rotation was found in the PMRA files, the registrant is requested to submit crop rotation data for validation.

The USEPA Human Health Risk Assessment indicated that the confined/field rotational crop requirements are fulfilled. Available information indicated that Dimethoate and Omethoate residues do not accumulate above 0.01 ppm in rotational crops at 30 day plant back intervals.

The JMPR and EFSA review of a confined crop rotational study indicated that total residues were 0.03 ppm in lettuce, 0.008 ppm in turnips, 0.021 ppm in wheat grain, when these crops were planted in a sandy loam soil 30 days after 0.56 kg a.i./ha was incorporated into the soil. Characterization of residues indicated that a majority of total radioactive residue (TRRs) were polar compounds. It was concluded that under field conditions, residues of Dimethoate and Omethoate would be <0.01 ppm in rotational crops.

Based on the USEPA, EFSA, and JMPR conclusions, Dimethoate and Omethoate residues are not expected to occur in significant amounts in rotational crops. A 30 day plant back interval is recommended on all labels as TRR in lettuce and wheat was >0.01 ppm.

7.0 Processing

Processing studies for potatoes, tomato, and wheat were available on file with the PMRA. The USEPA (2002) has accepted these studies along with additional processing studies for citrus (orange juice, dried citrus pulp), field corn, cottonseed, and safflower. JMPR (2003) has reviewed additional processing studies for cabbage and olives.

Based on existing studies, the USEPA concluded that separate tolerances were not required to cover residues of Dimethoate and Omethoate in processing fractions of corn (field), cottonseed, oranges, potatoes, tomatoes and wheat. Data indicated that a tolerance was required for dried citrus pulp. The American assessment also indicated that a processing study was not required for soybeans since residues were not detectable in RAC following a treatment at 5× GAP.

The only Canadian use patterns not covered by the American assessment of processing studies are flax and canola. The registrant indicated that there is no specific data available for these crops. In the USEPA Dimethoate Registration Standard (September 30, 1982), it was determined that residue data was not required for soybean processed fractions because residues in the RAC were <0.1 ppm when 0.56-2.8 kg a.i./ha was applied 3 times with PHIs of 20-24 days. This is

6.5-40× Canadian GAP rate for canola and flax. The PMRA will not ask for canola and flax processing studies but will request the safflower processing study be submitted in order to assess the potential for residues in canola and flax processed fractions.

JMPR (2003) concluded that raw and refined olive oil had lower levels of Dimethoate and Omethoate residues (1-43% of the residue found in RAC) compared to the RAC. Additionally, residues of both compounds were lower in canned olives and declined during the storage of olives prior to processing (3-91% of the residue found in RAC). For processed cabbages, both Dimethoate and Omethoate residues significantly decreased during cook and declined to levels that were below 20% of the residues found on the RAC.

In summary, the safflower processing study and their respective DERs should be requested from the registrant and reviewed. The safflower processing study will be reviewed to determine the potential for residues in processed fractions of safflower, canola and flax.

Kitchen processing studies

Several authors in the open literature have investigated the effect of kitchen-processing on concentrations of Dimethoate residues in foods (EPA, 2002a). Based on the results of these studies, a cooking factor of 0.7 (30% reduction of residues by cooking) for any cooked form of vegetables and fruits (with exception of cabbage - 20% processing factor), and a cooking factor of 0.8 (20% reduction of residues by cooking) for any cooked forms of grains were applied in the assessment. Since most residue data for vegetables and fruits used in this assessment were from USDA PDP monitoring data, and these type of data are obtained from washed and peeled (where appropriate) fruits and vegetables, no washing or peeling reduction factors were generally used in this risk assessment. No cooking studies for Dimethoate in meat were found. A cooking study of several other organophosphate pesticides in meat was found, and showed that cooking causes decomposition of the substances tested. Based on the results of this study, a cooking factor of 0.7 (i.e. 30% reduction of residues by cooking) for any cooked form of meat was applied in the calculation.

Appendix X Supplemental Maximum Residue Limit Information—International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data. For animal commodities, differences in MRLs can be due to different livestock feed items and practices.

Under the North American Free Trade Agreement, Canada, the United States and Mexico are committed to resolving MRL discrepancies to the broadest extent possible. Harmonization will standardize the protection of human health across North America and promote the free trade of safe food products. Until harmonization is achieved, the Canadian MRLs and regulatory amendments presented in this document are necessary. The differences in MRLs/tolerances outlined above are not expected to impact businesses negatively or adversely affect international competitiveness of Canadian firms or to negatively affect any regions of Canada.

Revocation of the Canadian MRL for apples, cabbage, and spinach is recommended as Dimethoate use on these commodities have been voluntary discontinued by the registrant in both Canada and the United States. In addition, the MRL for lettuce should be change to specify to lettuce (leaf) only as use on lettuce (head) has also been discontinued. Canadian MRLs for other commodities will be revised or confirmed after adequate data has been provided.

Table 1 Comparison between MRLs in Canada and in Other Jurisdictions

Crop	Registered Use in Canada	Canadian MRL[1,2] (PPM)	American Tolerance[1] (PPM)	CODEX MRL[1] (PPM)
Food Crops				
Apples		**2**	**REVOKED**	
Artichoke (globe)				0.05
Asparagus	✓		0.15	0.05
Barley	✓			2
Beans	✓	1	2	
Beets (tops)	✓	2		
Beets (sugar)				0.05
Blueberries	✓	1	1	
Broccoli	✓	2	2	

Crop	Registered Use in Canada	Canadian MRL^{1,2} (PPM)	American Tolerance^{1} (PPM)	CODEX MRL^{1} (PPM)
Brussel Sprouts	✓		5	0.2
Cabbages		**2**	**REVOKED**	0.05
Cabbage Chinese	✓			
Canola	✓			
Cauliflower	✓	2	2	2
Celery	✓	1	2	0.5
Cherries	✓	2	2	2
Chicory	✓			
Chinese Broccoli	✓			
Citrus fruits		1.5		5
Collards			**REVOKED**	
Corn (grain)			0.1	
Cottonseed			0.1	
Eggplant	✓			
Endive			2	
Flax	✓			
Filbert/Hazelnut	✓			
Grapes			**REVOKED**	
Grapefruit		1.5[4]	2	5[4]
Kale	✓	2	2	
Lemon		1.5[4]	2	5[4]
Lentils			**REVOKED**	
Lettuce	✓	**2**	**Specified to Lettuce (Leaf)**	2
Mangos				1

Crop	Registered Use in Canada	Canadian MRL[1,2] (PPM)	American Tolerance[1] (PPM)	CODEX MRL[1] (PPM)
Melons[3]			1	
Mustard Greens			2	
Oats	✓			
Olives				0.5
Orange		1.5[4]	2	5[4]
Peaches (non-bearing)	✓			
Pears	✓	2		1
Peas	✓	0.5	2	1
Pecans			0.1	
Peppers	✓	0.5	2	1
Potatoes	✓		0.2	0.05
Rye	✓			
Safflower	✓		0.1	
Spinach		**2**	**REVOKED**	
Sorghum (grain)			0.1	
Soybeans (grain)	✓		0.05	
Strawberries	✓	1		
Swiss Chard	✓	2	2	
Tangerines		1.5[4]	2	5[4]
Tomatoes	✓	0.5	2	
Turnip (tops)	✓	2	2	1
Turnip (roots)			0.2	0.1
Wheat	✓		0.04	0.05

Crop	Registered Use in Canada	Canadian MRL[1,2] (PPM)	American Tolerance[1] (PPM)	CODEX MRL[1] (PPM)
Animal Commodities				
Meat (beef, pork, sheep, poultry, etc)			0.02	0.05
Eggs			0.02	0.05
Milk			TBD	0.05
Animal Feed				
Alfalfa	✓		2	
Corn (stover, forage)			1	
Cowpea (forage, hay)			TBD	
Dried citrus pulp			5	
Peas (field, hay, vines)			TBD	
Sorghum (fodder, forage)			0.1	
Soybean (forage, hay)			2	
Wheat (stover, hay, straw)			2	

TBD = to be determined

[1] EPA Tolerances were obtained from the Electronic Code of Regulations. CODEX MRLs were obtained from the CODEX alimentarius. Canadian MRL and American tolerance includes both Dimethoate and Omethoate residues in the definition. CODEX MRLs include Dimethoate residues only.

[2] Commodities that do not have specific Canadian MRLs are covered under the general MRL at 0.1 ppm.

[3] Melons include cantaloupe, honeydew, watermelon.

[4] Covered by citrus MRL.

Appendix XI Environmental Fate and Toxicity

Table 1 Environmental fate of Dimethoate

Study type	Test material	Study Conditions	Value or Endpoint	Comments	Major transformation products	Reference
Abiotic transformation						
Hydrolysis	^{14}C-Dimethoate	30 d	pH 5 156 d pH 7 68 d pH 9 4.4 d	Stable under acidic & neutral conditions		PMRA 1203562
Phototransformation - soil	^{14}C-Dimethoate	30 d under sunlight	irradiated: 10.5 d dark control: 7.9 d	Not a major route of transformation	dimethylphosphoric acid, dimethylthiophosphoric acid	PMRA 1415508 PMRA 1415510
		15 d under artificial light (equiv. of 30 d sunlight)	irradiated: 7-16 d dark control: 40 d		dimethylphosphoric acid, dimethoxon	PMRA 1216511
Phototransformation - water	^{14}C-Dimethoate	15 d under artificial light (equiv. of 30 d sunlight), pH 5	Half-life 175 d	Not a major route of transformation		PMRA 1203563
Biotransformation						
Soil - aerobic	^{14}C-Dimethoate	Sandy loam	DT$_{50}$ 2.2 d DT$_{90}$ 7.5 d	Non persistent[1]	desmethyl Dimethoate, dimethylthiophosphoric acid	PMRA 1415508 PMRA 1415510
		Clay loam	DT$_{50}$ 2.4 d DT$_{90}$ 8.0 d	Non persistent	trasformation products not identified	PMRA 1246253
		Silty clay	DT$_{50}$ 2.0 d DT$_{90}$ 6.8 d			
		Sandy loam	DT$_{50}$ 4.1 d DT$_{90}$ 13.5 d			
Soil - anaerobic	^{14}C-Dimethoate	Sandy loam	DT$_{50}$ 22 d	Non persistent[1]	desmethyl Dimethoate, dimethylthiophosphoric acid	PMRA 1415508 PMRA 1415510
Water/sediment - aerobic	^{14}C-Dimethoate	105 d @20±2°C; two systems (river & pond)	DT$_{50}$/DT$_{90}$ of 17.2/57.2 d (river whole system) DT$_{50}$/DT$_{90}$ of 13.2/43.8 d (pond whole system) DT$_{50}$/DT$_{90}$ of 14.8/49.1 d (river water) DT$_{50}$/DT$_{90}$ of 12.5/41.5 d (pond water)	Non persistent	desmethyl Dimethoate	PMRA 1191021

Study type	Test material	Study Conditions	Value or Endpoint	Comments	Major transformation products	Reference
Mobility						
Soil column leaching	^{14}C-Dimethoate	Aged soils	K_d/K_{oc} sand 0.06/6.7 sandy loam 0.30/20 silt loam 0.57/16.2 loam 0.74/10	High to very high mobility^2	dimethylphosphoric acid	PMRA 1216496
Volatility	^{14}C-Dimethoate (EC formulation)	2.24 kg/ha on loamy sand ; 30 d	1.29 μg/m^3 (mean daily concentration in air)	Non volatile		PMRA 1415508 PMRA 1415510
		soil and bush beans	>20% volatilization after 24 h			PMRA 1246255
Field studies						
Field dissipation	Clean Crop Dimethoate 25W	Waterloo, NY; sandy loam; rate of 4.5 kg a.i./ha	Half-life 5 d No residues were found below the 15-30 cm layer	Not mobile	dimethoxone (Omethoate) at 0.017 ppm (no residues found below the 0-15 cm layer)	PMRA 1415508 PMRA 1415510

[1] classified according to the classification of Goring et al (1975)

[2] classified according to the classification of McCall et al (1981)

McCall, J.P., D.A. Laskowski, R.L. Swann and J.J. Dishburger. (1981). Measurement of sorption coefficients of organic chemicals and their use in environmental fate analysis. Pages 89 - 109 *IN* Test protocols for environmental fate and movement of toxicants. Proceedings of a symposium. Association of Official Analytical Chemists. 94th Annual Meeting, October 21 - 22, 1980 Washington, DC.

McEwen, F.L., and G.R. Stephenson (1979) The use and significance of pesticides in the environment. John Wiley and Sons Inc. Toronto. 282 pp.

Table 2 Environmental toxicity of Dimethoate

Organism	Study type	Species	Test material	Endpoint	Value	Reference
Terrestrial Species						
Invertebrate	Acute oral	Honey bee	Dimethoate Technical	48-h LD_{50}	0.05 μg a.i./bee	PMRA 1415508 PMRA 1415510
	Acute contact	Earthworm	Dimethoate Technical	14-d LC_{50} NOEC	84.5 mg a.i./kg soil 24.3 mg a.i./kg soil	PMRA 1191022
		Honey bee	Dimethoate Technical	48-h LD50	0.16 μg a.i./bee	PMRA 1415508 PMRA 1415510
		Parasitic wasp	Dimethoate (ECformulation)	LD_{50}	0.006 μg/animal	
		Ladybird beetle			1.6 μg/animal	

Organism	Study type	Species	Test material	Endpoint	Value	Reference
Birds	Acute oral	Mallard duck	Dimethoate Technical	LD_{50}	41.7-63.5 mg a.i./kg bw	PMRA 1415508 PMRA 1415510
		Ring-necked pheasant			20.0 mg a.i./kg bw	
		Red-winged blackbird			5.4 mg a.i./kg bw	
		European starling			32.0 mg a.i./kg bw	
		Domestic chicken			50.0 mg a.i./kg bw	
	Dietary	Mallard duck		LC_{50}	1011 mg a.i./kg diet	
		Japanese quail			346 mg a.i./kg diet	
		Ring-necked pheasant			332 mg a.i./kg diet	
	Chronic toxicity (reproduction)	Bobwhite quail		NOEC	4.0 mg a.i./kg diet	PMRA 1415508 PMRA 1415510
		Mallard duck		NOEC	35.4 mg a.i./kg diet	
Mammals	Acute oral	Rat	Dimethoate Technical	LD_{50}	250 mg a.i./kg bw	PMRA 1415508 PMRA 1415510
		Mouse		LD_{50}	120 mg a.i./kg bw	
		Rat		LD_{50}	310 mg a.i./kg bw	HED Review
		Mouse		LD_{50}	160 mg a.i./kg bw	
	Dietary	Rat		NOEL	32 mg a.i./kg diet	PMRA 1415508 PMRA 1415510
	Chronic toxicity (reproduction)	Rat	Dimethoate Technical	NOEL	1.2 mg a.i./kg bw/day	HED Review

Organism	Study type	Species	Test material	Endpoint	Value	Reference
Freshwater Organisms						
Invertebrate	Acute	*Daphnia magna*	Dimethoate Technical	48-h EC_{50}	3.32 mg a.i./L	PMRA 1415508 PMRA 1415510
		Stonefly			0.043 mg a.i./L	
		Scud			0.20 mg a.i./L	
		Yellow fever mosquito			5.04 mg a.i./L	
	Chronic	*Daphnia magna*	Dimethoate Technical	21-d NOEC	NOEC=0.04 mg a.i./L	
Fish	Acute	Rainbow trout	Dimethoate Technical	96-h LC_{50}	6.2-7.5 mg a.i./L	PMRA 1415508 PMRA 1415510
		Bluegill sunfish			6.0 mg a.i./L	
		Goldfish	30.5% formulated product	48-h LC_{50}	180 mg a.i./L	
	Chronic (Early Life Stage)	Rainbow trout		NOEC LOEC	0.43 mg a.i./L 0.84 mg a.i./L	
Marine/Estuarine organisms						
Invertebrate	Acute	Eastern oyster	Dimethoate Technical	96-h LC_{50}	113 mg a.i./L	PMRA 1415508 PMRA 1415510
		Mysid shrimp			15 mg a.i./L	
		Brown shrimp		48-h LC_{50}	>1.0 mg a.i./L	
		Brine shrimp			15.7 mg a.i./L	
		Saltmarsh mosquito			0.031 mg a.i./L	
Fish	Acute	Sheepshead minnow	Dimethoate Technical	96-h LC_{50}	>111 mg a.i./L	PMRA 1415508 PMRA 1415510
		Longnose killfish		48-h LC_{50}	>1.0 mg a.i./L	

Table 3 Screening Level Risk Assessment for Terrestrial Organisms Other than Birds and Mammals

Organism	Exposure	Endpoint value	Applic. Rate	EEC [1]	RQ[3]	LOC[4] exceeded
Invertebrates						
Earthworm	Acute Oral	NOEC: 62.5 mg a.i./kg soil	205 g a.i./ha	0.09 mg a.i./kg soil	< 0.1	No
			1553.4 g a.i./ha	0.69 mg a.i./kg soil	<0.1	No
			6000 g a.i./ha	2.7 mg a.i./kg soil	0.1	No
Bee	Acute Oral	LD_{50} 0.05 µg a.i./bee (0.056 kg a.i./ha[2])	205 g a.i./ha	205 g a.i./ha	4	Yes
	Acute Contact	LD_{50} 0.16 µg a.i./bee (0.18 kg a.i./ha[2])			1.1	Yes
Parasitic wasp	Acute Contact	LD_{50} 0.006 µg a.i./animal (0.0067 kg a.i./ha[2])			30	Yes

[1] Environmental Exposure Concentration (Soil: calculated based on a soil density of 1.5 g/cm^3, soil depth of 15 cm and the label rates taking into consideration dissipation between applications; Bee: maximum individual application rate; Parasitic wasp and vascular plants: maximum application rate not taking into consideration dissipation between applications)

[2] Toxicity in µg/bee converted to the equivalent kg a.i./ha using a conversion factor of 1.12 (Atkins et al., 1981)

[3] Risk Quotient (RQ) = exposure/toxicity

[4] Level of Concern (LOC) = RQ = 1; a calculated RQ > 1 exceeds the LOC

Atkins EL; Kellum D; Atkins KW. 1981. Reducing pesticide hazards to honey bees: mortality prediction techniques and integrated management techniques. Univ Calif, Div Agric Sci, Leaflet 2883. 22 pp.

Table 4 Screening Level Risk Assessment for Birds and Mammals

Organism	Exposure	Endpoint value[1]	Feeding Guilds	Exposure[4]		RQ[5]	LOC exceeded
				EEC (mg a.i./kg diet)	EDE (mg a.i./kg bw)		
Application rate 205 g a.i./ha							
Birds							
Bird: 20 g	Acute	LD50/10 0.54 mg a.i./kg bw	Insectivore	40.51	10.28	19	Yes
			Granivore	6.93	1.76	3.25	Yes
			Frugivore	20.88	5.3	9.8	Yes
	Dietary	LD50/10 4.65 mg a.i./kg bw[2]	Insectivore	40.51	10.28	2.2	Yes
			Granivore	6.93	1.76	0.4	No
			Frugivore	20.88	5.3	1.1	Yes
	Reproduction	NOEL = 0.22 mg a.i./kg bw/day[3]	Insectivore	40.51	10.28	46	Yes
			Granivore	6.93	1.76	8	Yes
			Frugivore	20.88	5.3	24	Yes

Organism	Exposure	Endpoint value[1]	Feeding Guilds	Exposure[4]		RQ[5]	LOC exceeded
				EEC (mg a.i./kg diet)	EDE (mg a.i./kg bw)		
Bird: 100 g	Acute	LD50/10 0.54 mg a.i./kg bw	Insectivore	40.51	8.08	15	Yes
			Granivore	6.93	1.38	2.5	Yes
			Frugivore	20.88	4.16	7.7	Yes
	Dietary	LD50/10 4.65 mg a.i./kg bw[2]	Insectivore	40.51	8.08	1.7	Yes
			Granivore	6.93	1.38	0.3	No
			Frugivore	20.88	4.16	0.9	No
	Reproduction	NOEL = 0.22 mg a.i./kg bw/day[3]	Insectivore	40.51	8.08	36.7	Yes
			Granivore	6.93	1.38	6.3	Yes
			Frugivore	20.88	4.16	18.9	Yes
Bird: 1000 g	Acute	LD50/10 0.54 mg a.i./kg bw	Insectivore	40.51	2.35	4	Yes
			Granivore	6.93	0.4	0.7	No
			Frugivore	20.88	1.21	2.2	Yes
			Herbivore	252.56	14.68	27	Yes
	Dietary	LD50/10 4.65 mg a.i./kg bw[2]	Insectivore	40.51	2.35	0.5	No
			Granivore	6.93	0.4	<0.1	No
			Frugivore	20.88	1.21	0.3	No
			Herbivore	252.56	14.68	3.2	Yes
	Reproduction	NOEL = 0.22 mg a.i./kg bw/day[3]	Insectivore	40.51	2.35	10.6	Yes
			Granivore	6.93	0.4	1.8	Yes
			Frugivore	20.88	1.21	5.5	Yes
			Herbivore	252.56	14.68	66	Yes
Mammals							
Mammal: 15 g	Acute	LD50/10 60 mg a.i./kg bw	Insectivore	40.51	5.89	0.1	No
			Granivore	6.93	1	<0.1	No
			Frugivore	20.88	3.03	<0.1	No
	Dietary	NOEL = 4.7 mg a.i./kg bw/day[3]	Insectivore	40.51	5.89	1.25	Yes
			Granivore	6.93	1	0.2	No
			Frugivore	20.88	3.03	0.6	No
	Reproduction	NOEL = 1.2 mg a.i./kg bw/day	Insectivore	40.51	5.89	4.9	Yes
			Granivore	6.93	1	0.8	No
			Frugivore	20.88	3.03	2.5	Yes

Organism	Exposure	Endpoint value[1]	Feeding Guilds	Exposure[4]		RQ[5]	LOC exceeded
				EEC (mg a.i./kg diet)	EDE (mg a.i./kg bw)		
Mammal: 35 g	Acute:	LD50/10 60 mg a.i./kg bw	Insectivore	40.51	5.06	<0.1	No
			Granivore	6.93	0.865	<0.1	No
			Frugivore	20.88	2.61	<0.1	No
			Herbivore	252.56	31.53	0.5	No
	Dietary	NOEL = 4.7 mg a.i./kg bw/day[3]	Insectivore	40.51	5.06	1.1	Yes
			Granivore	6.93	0.865	0.2	No
			Frugivore	20.88	2.61	0.55	No
			Herbivore	252.56	31.53	6.7	Yes
	Reproduction	NOEL = 1.2 mg a.i./kg bw/day[3]	Insectivore	40.51	5.06	4.2	Yes
			Granivore	6.93	0.865	0.7	No
			Frugivore	20.88	2.61	2.2	Yes
			Herbivore	252.56	31.53	26	Yes
Mammal: 1000 g	Acute	LD50/10 60 mg a.i./kg bw	Insectivore	40.51	2.78	<0.1	No
			Granivore	6.93	0.48	<0.1	No
			Frugivore	20.88	1.43	<0.1	No
			Herbivore	252.56	17.35	0.3	No
	Dietary	NOEL = 4.7 mg a.i./kg bw/day[3]	Insectivore	40.51	2.78	0.6	No
			Granivore	6.93	0.48	0.1	No
			Frugivore	20.88	1.43	0.3	No
			Herbivore	252.56	17.35	3.7	Yes
	Reproduction	NOEL = 1.2 mg a.i./kg bw/day[3]	Insectivore	40.51	2.78	2.3	Yes
			Granivore	6.93	0.48	0.4	No
			Frugivore	20.88	1.43	1.2	Yes
			Herbivore	252.56	17.35	14.45	Yes
Application rate 1553.4 g a.i./ha*							
Birds							
Bird: 20 g	Acute	LD50/10 0.54 mg a.i./kg bw	Insectivore	306.95	78.3	145	Yes
			Granivore	52.53	13.4	25	Yes
			Frugivore	158.2	40.3	75	Yes
	Dietary	LD50/10 4.65 mg a.i./kg bw[2]	Insectivore	306.95	78.3	17	Yes
			Granivore	52.53	13.4	3	Yes
			Frugivore	158.2	40.3	8.7	Yes
	Reproduction	NOEL = 0.22 mg a.i./kg bw/day[3]	Insectivore	306.95	78.3	356	Yes
			Granivore	52.53	13.4	61	Yes
			Frugivore	158.2	40.3	183	Yes

Organism	Exposure	Endpoint value[1]	Feeding Guilds	Exposure[4]		RQ[5]	LOC exceeded
				EEC (mg a.i./kg diet)	EDE (mg a.i./kg bw)		
Bird: 100 g	Acute	LD50/10 0.54 mg a.i./kg bw	Insectivore	306.95	61.1	113	Yes
			Granivore	52.53	10.5	19	Yes
			Frugivore	158.2	31.5	58	Yes
	Dietary	LD50/10 4.65 mg a.i./kg bw[2]	Insectivore	306.95	61.1	1.3	Yes
			Granivore	52.53	10.5	2.25	Yes
			Frugivore	158.2	31.5	6.8	Yes
	Reproduction	NOEL = 0.22 mg a.i./kg bw/day[3]	Insectivore	306.95	61.1	278	Yes
			Granivore	52.53	10.5	47.5	Yes
			Frugivore	158.2	31.5	143	Yes
Bird: 1000 g	Acute	LD50/10 0.54 mg a.i./kg bw	Insectivore	306.95	17.8	33	Yes
			Granivore	52.53	3.1	6	Yes
			Frugivore	158.2	9.2	17	Yes
			Herbivore	1913.78	111.2	206	Yes
	Dietary	LD50/10 4.65 mg a.i./kg bw[2]	Insectivore	306.95	17.8	3.8	Yes
			Granivore	52.53	3.1	0.7	No
			Frugivore	158.2	9.2	2	Yes
			Herbivore	1913.78	111.2	2.4	Yes
	Reproduction	NOEL = 0.22 mg a.i./kg bw/day[3]	Insectivore	306.95	17.8	81	Yes
			Granivore	52.53	3.1	14	Yes
			Frugivore	158.2	9.2	42	Yes
			Herbivore	1913.78	111.2	505	Yes
Mammals							
Mammal: 15 g	Acute	LD50/10 60 mg a.i./kg bw	Insectivore	306.95	45	0.8	No
			Granivore	52.53	7.7	0.1	No
			Frugivore	158.2	23.2	0.3	No
	Dietary	NOEL = 4.7 mg a.i./kg bw/day[3]	Insectivore	306.95	45	9.6	Yes
			Granivore	52.53	7.7	1.6	Yes
			Frugivore	158.2	23.2	5	Yes
	Reproduction	NOEL = 1.2 mg a.i./kg bw/day	Insectivore	306.95	45	37.5	Yes
			Granivore	52.53	7.7	6	Yes
			Frugivore	158.2	23.2	19	Yes

Organism	Exposure	Endpoint value[1]	Feeding Guilds	Exposure[4]		RQ[5]	LOC exceeded
				EEC (mg a.i./kg diet)	EDE (mg a.i./kg bw)		
Mammal: 35 g	Acute:	LD50/10 60 mg a.i./kg bw	Insectivore	306.95	39.5	0.7	No
			Granivore	52.53	6.8	0.1	No
			Frugivore	158.2	20.3	0.3	No
			Herbivore	1913.78	246.1	4	Yes
	Dietary	NOEL = 4.7 mg a.i./kg bw/day[3]	Insectivore	306.95	39.5	8.4	Yes
			Granivore	52.53	6.8	1.4	Yes
			Frugivore	158.2	20.3	4.3	Yes
			Herbivore	1913.78	246.1	52	Yes
	Reproduction	NOEL = 1.2 mg a.i./kg bw/day[3]	Insectivore	306.95	39.5	33	Yes
			Granivore	52.53	6.8	5.6	Yes
			Frugivore	158.2	20.3	17	Yes
			Herbivore	1913.78	246.1	205	Yes
Mammal: 1000 g	Acute	LD50/10 60 mg a.i./kg bw	Insectivore	306.95	21.1	0.4	No
			Granivore	52.53	3.6	0.1	No
			Frugivore	158.2	10.9	0.2	No
			Herbivore	1913.78	131.5	2	Yes
	Dietary	NOEL = 4.7 mg a.i./kg bw/day[3]	Insectivore	306.95	21.1	4.5	Yes
			Granivore	52.53	3.6	0.8	No
			Frugivore	158.2	10.9	2.3	Yes
			Herbivore	1913.78	131.5	28	Yes
	Reproduction	NOEL = 1.2 mg a.i./kg bw/day[3]	Insectivore	306.95	21.1	18	Yes
			Granivore	52.53	3.6	3	Yes
			Frugivore	158.2	10.9	9	Yes
			Herbivore	1913.78	131.5	110	Yes
Application rate 6000 g a.i./ha							
Birds							
Bird: 20 g	Acute	LD50/10 0.54 mg a.i./kg bw	Insectivore	1185.59	301.02	557	Yes
			Granivore	202.92	51.52	95	Yes
			Frugivore	611.04	155.14	287	Yes
	Dietary	LD50/10 4.65 mg a.i./kg bw[2]	Insectivore	1185.59	301.02	65	Yes
			Granivore	202.92	51.52	11	Yes
			Frugivore	611.04	155.14	33	Yes
	Reproduction	NOEL = 0.22 mg a.i./kg bw/day[3]	Insectivore	1185.59	301.02	1368	Yes
			Granivore	202.92	51.52	234	Yes
			Frugivore	611.04	155.14	705	Yes

Organism	Exposure	Endpoint value[1]	Feeding Guilds	Exposure[4]		RQ[5]	LOC exceeded
				EEC (mg a.i./kg diet)	EDE (mg a.i./kg bw)		
Bird: 100 g	Acute	LD50/10 0.54 mg a.i./kg bw	Insectivore	1185.59	236.53	438	Yes
			Granivore	202.92	40.48	75	Yes
			Frugivore	611.04	121.9	225	Yes
	Dietary	LD50/10 4.65 mg a.i./kg bw[2]	Insectivore	1185.59	236.53	5	Yes
			Granivore	202.92	40.48	8.7	Yes
			Frugivore	611.04	121.9	3	Yes
	Reproduction	NOEL = 0.22 mg a.i./kg bw/day[3]	Insectivore	1185.59	236.53	1075	Yes
			Granivore	202.92	40.48	184	Yes
			Frugivore	611.04	121.9	554	Yes
Bird: 1000 g	Acute	LD50/10 0.54 mg a.i./kg bw	Insectivore	1185.59	68.91	127	Yes
			Granivore	202.92	11.79	3.3	Yes
			Frugivore	611.04	35.51	65.75	Yes
			Herbivore	7392	429.62	795	Yes
	Dietary	LD50/10 4.65 mg a.i./kg bw[2]	Insectivore	1185.59	68.91	1.5	Yes
			Granivore	202.92	11.79	0.25	No
			Frugivore	611.04	35.51	0.8	No
			Herbivore	7392	429.62	9	Yes
	Reproduction	NOEL = 0.22 mg a.i./kg bw/day[3]	Insectivore	1185.59	68.91	313	Yes
			Granivore	202.92	11.79	53.5	Yes
			Frugivore	611.04	35.51	161	Yes
			Herbivore	7392	429.62	1952	Yes
Mammals							
Mammal: 15 g	Acute	LD50/10 60 mg a.i./kg bw	Insectivore	1185.59	172.31	3	Yes
			Granivore	202.92	29.49	0.5	No
			Frugivore	611.04	88.8	1.5	Yes
	Dietary	NOEL = 4.7 mg a.i./kg bw/day[3]	Insectivore	1185.59	172.31	37	Yes
			Granivore	202.92	29.49	6	Yes
			Frugivore	611.04	88.8	19	Yes
	Reproduction	NOEL = 22.9 mg a.i./kg bw/day[3]	Insectivore	1185.59	172.31	7.5	Yes
			Granivore	202.92	29.49	1.3	Yes
			Frugivore	611.04	88.8	4	Yes

Organism	Exposure	Endpoint value[1]	Feeding Guilds	Exposure[4]		RQ[5]	LOC exceeded
				EEC (mg a.i./kg diet)	EDE (mg a.i./kg bw)		
Mammal: 35 g	Acute:	LD50/10 60 mg a.i./kg bw	Insectivore	1185.59	148.03	2.5	Yes
			Granivore	202.92	25.36	0.4	No
			Frugivore	611.04	76.29	1.3	Yes
			Herbivore	7392	922.94	15	Yes
	Dietary	NOEL = 4.7 mg a.i./kg bw/day[3]	Insectivore	1185.59	148.03	31.5	Yes
			Granivore	202.92	29.49	6	Yes
			Frugivore	611.04	76.29	16	Yes
			Herbivore	7392	922.94	196	Yes
	Reproduction	NOEL = 22.9 mg a.i./kg bw/day[3]	Insectivore	1185.59	148.03	6.5	Yes
			Granivore	202.92	29.49	1.3	Yes
			Frugivore	611.04	76.29	3.3	Yes
			Herbivore	7392	922.94	40	Yes
Mammal: 1000 g	Acute	LD50/10 60 mg a.i./kg bw	Insectivore	1185.59	81.47	1.35	Yes
			Granivore	202.92	13.94	0.2	No
			Frugivore	611.04	41.99	0.7	No
			Herbivore	7392	507.97	8.5	Yes
	Dietary	NOEL = 4.7 mg a.i./kg bw/day[3]	Insectivore	1185.59	81.47	17	Yes
			Granivore	202.92	13.94	3	Yes
			Frugivore	611.04	41.99	9	Yes
			Herbivore	7392	507.97	108	Yes
	Reproduction	NOEL = 22.9 mg a.i./kg bw/day[3]	Insectivore	1185.59	81.47	3.5	Yes
			Granivore	202.92	13.94	0.6	No
			Frugivore	611.04	41.99	1.8	Yes
			Herbivore	7392	507.97	22	Yes

[1] Endpoints were divided by an Uncertainty Factor to account for varying protection goals (i.e. protection at the community, population, or individual level)

[2] Conversion from a concentration (EEC) to a dose (EDE): [EDE (mg a.i./kg bw) = EEC (mg a.i./kg diet)/BW (g) × FIR (g diet/day)]

[3] Conversion of NOEL from a concentration to a dose (see above)

[4] EEC: For birds and mammals, the EEC takes into account the maximum seasonal cumulative rate on vegetation and is calculated using PMRA standard methods based on the Hoerger and Kenaga nomogram as modified by Fletcher (1994)
EDE = Estimated dietary exposure; calculated for each bird or mammal size based on the EEC on appropriate food item for each food guild (at the screening level, the most conservative EEC for each food guild was used). The EDE was calculated using the following formula: (FIR/BW) × EEC. For each body weight (BW), the food ingestion rate (FIR) was based on equations from Nagy (1987). For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used; for mammals, the "all mammals" equation was used:
Passerine Equation (body weight ≤200 g): FIR (g dry weight/day) = 0.398(BW in g) 0.850
All Birds Equation (body weight > 200 g): FIR (g dry weight/day) = 0.648(BW in g) 0.651
All Mammals Equation: FIR (g dry weight/day) = 0.235(BW in g) 0.822

[5] RQ = exposure/toxicity; RQs < 0.1 were not calculated to show all decimal points

[6] Cumulative rate based on 2 applications at 1320 g a.i./ha, 10 d interval, and foliar half-life (Willis and McDowell, 1987) of 4 d.

Nagy, K.A. 1987. Field metabolic rate and food requirement scaling in mammals and birds. Ecological Monographs 57:111-128
Willis, G.H. and McDowell, L.L. 1987. Pesticide persistence on foliage in Reviews of Environmental Contamination and Toxicology. Vol. 100, ed. G.W. Ware, Springer-Verlag New York Inc.

Table 5 Screening Level Risk Assessment of Dimethoate to Aquatic Organisms

Organism	Exposure	Endpoint value[1] (mg a.i./L)	Use Rate (g a.i./ha)	EEC[2] (mg a.i./L)	RQ	LOC exceeded
Freshwater Species						
D. magna	Acute	LC_{50} = 1.66	205	0.025	<0.1	No
			1553.43	0.27	0.2	No
			6000	0.75	0.45	No
Stonefly		LC_{50} = 0.0215	205	0.025	1.2	Yes
			1553.4	0.27	12.5	Yes
			6000	0.75	35	Yes
Scud		LC_{50} = 0.1	205	0.025	0.25	No
			1553.4	0.27	2.7	Yes
			6000	0.75	7.5	Yes
Yellow fever mosquito		LC_{50} = 2.5	205	0.025	<0.1	No
			1553.4	0.27	0.1	No
			6000	0.75	0.3	No
D. magna	Chronic	NOEC = 0.04	205	0.025	0.6	No
			1553.4	0.27	6.75	Yes
			6000	0.75	18.75	Yes
Rainbow trout	Acute	LC_{50} = 0.62	205	0.025	<0.1	No
			1553.4	0.27	0.4	No
			6000	0.75	1.2	Yes
Bluegill sunfish		LC_{50} = 0.6	205	0.025	<0.1	No
			1553.4	0.27	0.45	No
			6000	0.75	1.25	Yes
Rainbow trout (Early Life Cycle)	Chronic	NOEC = 0.43	205	0.025	<0.1	No
			1553.4	0.27	0.6	No
			6000	0.75	1.7	Yes
Amphibian[4]	Acute	LC_{50} = 0.6	205	0.14	0.2	No
			1553.4	1.43	2.4	Yes
			6000	4	6.7	Yes
	Chronic	NOEC = 0.43	205	0.14	0.3	No
			1553.4	1.43	3.3	Yes
			6000	4	9	Yes

Organism	Exposure	Endpoint value[1] (mg a.i./L)	Use Rate (g a.i./ha)	EEC[2] (mg a.i./L)	RQ	LOC exceeded
Marine Species						
Saltmarsh mosquito	Acute	LC_{50} = 0.015	205	0.025	1.7	Yes
			1553.4	0.27	18	Yes
			6000	0.75	50	Yes
Longnose killifish		LC_{50} = 0.1	205	0.025	0.25	No
			1553.4	0.27	2.7	Yes
			6000	0.75	7.5	Yes

[1] Endpoints were divided by an Uncertainty Factor to account for varying protection goals (i.e. protection at the community, population, or individual level)

[2] EEC based on a 15 cm water body depth for amphibians and a 80 cm water depth for all other aquatic organisms.

[3] Cumulative rate (2 applications of 1320 g a.i./ha with the interval of 10 d)

[4] Endpoints from fish as surrogate.

Table 6 Refined Risk Assessment for Birds and Mammals (Off-field, spray drift)

Organism	Exposure	Toxicity	Feeding Guild	EDE[1] (mg a.i./kg bw)		RQ		LOC exceeded	
				11%	26%	11%	26%	11%	26%
Application rate 205 g a.i./ha									
Bird 20 g	Acute	$LD_{50/10}$ 0.54 mg a.i./kg bw	Insectivore	1.13	2.67	2.1	4.9	Yes	Yes
			Granivore	0.19	0.46	0.35	0.85	No	No
			Frugivore	0.58	1.38	1.1	2.5	Yes	Yes
	Dietary	$LD_{50/10}$ 4.65 mg a.i./kg bw	Insectivore	1.13	2.67	0.2	0.6	No	No
			Fructivore	0.58	1.38	0.1	0.3	No	No
	Reproduction	NOEL = 0.22 mg a.i./kg bw/day	Insectivore	1.13	2.67	5	12	Yes	Yes
			Granivore	0.19	0.46	0.9	2.1	No	Yes
			Frugivore	0.58	1.38	2.6	6.3	Yes	Yes
Bird 100 g	Acute	$LD_{50/10}$ 0.54 mg a.i./kg bw	Insectivore	0.9	2.1	1.7	3.9	Yes	Yes
			Granivore	0.15	0.36	0.3	0.7	No	No
			Frugivore	0.45	1.1	0.8	2	No	Yes
	Reproduction	NOEL = 0.22 mg a.i./kg bw/day	Insectivore	0.9	2.1	4	9.5	Yes	Yes
			Granivore	0.15	0.36	0.7	1.6	No	Yes
			Frugivore	0.45	1.1	2	5	Yes	Yes
Bird 1000 g	Acute	$LD_{50/10}$ 0.54 mg a.i./kg bw	Insectivore	0.9	2.1	1.7	3.9	Yes	Yes
			Herbivore	0.16	3.8	0.3	7	No	Yes
	Dietary	$LD_{50/10}$ 4.65 mg a.i./kg bw	Herbivore	0.16	3.8	<0.1	0.8	No	No
	Reproduction	NOEL = 0.22 mg a.i./kg bw/day	Insectivore	0.9	2.1	4	9.5	Yes	Yes
			Granivore	0.15	0.36	0.7	1.6	No	Yes
			Frugivore	0.45	1.1	2	5	Yes	Yes
			Herbivore	0.16	3.8	0.7	17	No	Yes
Mammal 15 g	Reproduction	NOEL = 1.2 mg a.i./kg bw/day	Insectivore	0.65	1.5	0.5	1.25	No	Yes
			Frugivore	0.33	0.8	0.3	0.7	No	No

Organism	Exposure	Toxicity	Feeding Guild	EDE[1] (mg a.i./kg bw)		RQ		LOC exceeded	
				11%	26%	11%	26%	11%	26%
Mammal 35 g	Dietary	NOEL = 4.7 mg a.i./kg bw/day	Insectivore	0.55	1.3	0.1	0.3	No	No
			Herbivore	3.5	8.2	0.7	1.7	No	Yes
	Reproduction	NOEL = 1.2 mg a.i./kg bw/day	Insectivore	0.55	1.3	0.45	1.1	No	Yes
			Frugivore	2.2	0.6	1.8	0.5	Yes	No
			Herbivore	3.5	8.2	2.9	6.8	Yes	Yes
Mammal 1000 g	Dietary	NOEL = 4.7 mg a.i./kg bw/day	Herbivore	1.9	4.5	0.4	0.95	No	No
	Reproduction	NOEL = 1.2 mg a.i./kg bw/day	Insectivore	0.3	0.7	0.25	0.6	No	No
			Frugivore	0.16	0.37	0.1	0.3	No	No
			Herbivore	1.9	4.5	1.6	3.75	Yes	Yes

[1] EDE calculated based on fine droplets for ground (11%) and aerial (26%) spray drift deposition.

Table 7 Refined Risk Assessment for Aquatic Organisms (Off-field, spray drift)

Organism	Exposure	Toxicity (mg a.i./L)	Applic. Rate (g a.i./ha)	EEC[1] (mg a.i./L)		RQ		LOC exceeded	
				11%	26%	11%	26%	11%	26%
Freshwater Species									
Stonefly	Acute	LC_{50} = 0.0215	205	0.003	0.007	0.13	0.3	No	No
			1553.4	0.03	0.07	1.4	3.25	Yes	Yes
			6000	0.08	0.195	3.7	9.1	Yes	Yes
D. magna	Chronic	NOEC = 0.04	1553.4	0.03	0.07	0.75	1.75	No	Yes
			6000	0.08	0.195	2	4.9	Yes	Yes
Bluegill sunfish	Acute	LC_{50} = 0.6	6000	0.08	0.195	0.13	0.325	No	No
Rainbow trout	Chronic (Early Life Cycle)	NOEC = 0.43	6000	0.08	0.195	0.2	0.45	No	No
Amphibian[2]	Acute	LC_{50} = 0.6	1553.4	0.16	0.37	0.3	0.6	No	No
			6000	0.4	1	0.7	1.7	No	Yes
	Chronic	NOEC = 0.43	1553.4	0.16	0.37	0.4	0.8	No	No
			6000	0.4	1	0.9	2.3	No	Yes
Marine Species									
Saltmarsh mosquito	Acute	LC_{50} = 0.015	1553.4	0.03	0.07	2	4.7	Yes	Yes
			6000	0.08	0.195	5.3	13	Yes	Yes

1 EEC (15 cm water body depth for amphibians and a 80 cm water depth for all other aquatic organisms) calculated based on spray drift deposition (fine droplets) for ground (11%) and aerial (26%) application rate.

2 Endpoints from fish as surrogate.

Table 8 Risk Assessment for Aquatic Organisms From Predicted Run-off

Toxicity endpoint	**EEC [µg a.i./L]**		**Endpoint [µg a.i./L]**	**RQ[1]**	
	Modelling*	**Monitoring****		**Modelling**	**Monitoring**
Freshwater Species					
Invertebrates					
Acute	252	2.9	21.5	11.7	0.13
Chronic	194	0.09	40	4.85	0.002
Amphibians[2]					
Acute	1338	2.9	600	2.2	0.005
Chronic	965	0.09	430	2.2	0.0002
Fish					
Acute	252	2.9	600	0.4	0.005
Chronic	194	0.09	430	0.45	0.0002
Marine/Estuarine Species					
Invertebrates					
Acute	252	2.9	15	16.8	0.2

* 90th percentile of peak and 21d runoff values for acute and for chronic, respectively.

** 95th percentile of the maximum detected concentrations from surface water monitoring studies and 95th percentile of the mean concentration for each study site including ½ LOD for non-detects for acute and chronic, respectively

1 Bold fonts indicates exceedance of LOC

2 Endpoints from fish as surrogate.

Appendix XII Dimethoate Aquatic Ecoscenario and Drinking Water Assessment

1.0 Introduction

The following sections provide the estimated environmental concentrations (EECs) of Dimethoate resulting from water modelling and the available water monitoring data with respect to environmental exposure and drinking water.

Monitoring data and modelling estimates provide different types of information, therefore are not directly comparable. Pesticide concentrations in water are highly variable in time and location, and Canadian monitoring data usually are sparse, so comparing monitoring results to modelling is not straightforward. Despite this, these two types of data are complementary and should be considered in conjunction with each other when considering the potential exposure of aquatic organisms or to humans through drinking water.

2.0 Modelling Estimates

2.1 Aquatic Ecoscenario Assessment: Level 1 Modelling

For Level 1 aquatic ecoscenario assessment, estimated environmental concentrations (EECs) of Dimethoate from runoff into a receiving water body were simulated using the PRZM/EXAMS models. The PRZM/EXAMS models simulate pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. For the Level 1 assessment, the water body consists of a 1 ha wetland with an average depth of 0.8 m and a drainage area of 10 ha. A seasonal water body was also used to assess the risk to amphibians, as a risk was identified at the screening level. This water body is essentially a scaled down version of the permanent water body noted above, but having a water depth of 0.15 m.

Dimethoate is an insecticide used on many crops at various application rates. The rate for use on ornamentals (a single application of 6 kg a.i./ha) was modelled. In addition three crop use patterns were modelled, canola (three applications of 0.432 kg a.i./ha seven days apart), potatoes (three applications of 0.528 kg a.i./ha seven days apart), and asparagus (six applications of 1.104 kg a.i./ha, 21 days apart). Application information and the main environmental fate characteristics used in the models are summarized in Table 1.

Several initial application dates, chosen appropriate to the crops being modelled, were modelled. The application date producing the largest EEC for each regional scenario is reported in Table 2. EECs are reported separately for the use on ornamentals and on crops. Deposition from spray drift was not included in the simulations, so these EECs are for the portion of the pesticide that enters the water body via runoff only. The model was run for 50 years for all scenarios.

Table 1 Major groundwater and surface water model inputs for Level 1 assessment of Dimethoate

Type of Input	Parameter	Value
Application Information	Crop(s) to be treated	ornamentals, asparagus, canola, potatoes
	Maximum allowable application rate per year (kg a.i./ha)	6.0 (ornamentals) 6.624 (asparagus) 1.296 (canola) 1.584 (potatoes)
	Maximum rate each application (kg a.i./ha)	6.0 (ornamentals) 1.104 (asparagus) 0.432 (canola) 0.534 (potatoes)
	Maximum number of applications per year	1 (ornamentals) 6 (asparagus) 3 (canola) 3 (potatoes)
	Minimum interval between applications (days)	7 (canola, potatoes) 21 (asparagus)
	Method of application	Aerial (surface water, and ecoscenario for canola) Ground (ecoscenario for ornamentals, asparagus, and potatoes)
Environmental Fate Characteristics	Hydrolysis half-life at pH 7 (days)	68
	Photolysis half-life in water (days)	175
	Adsorption K_{oc}(mL/g)	8.7 (20th percentile of four K_{oc} values)
	Aerobic soil biotransformation half-life (days)	3.1 (80th percentile of four half-life values)
	Aerobic aquatic biotransformation half-life (days)	17.2 (slowest of two half-lives)
	Anaerobic aquatic biotransformation half-life (days)	stable (no data)

The EECs (Table 2) are calculated from the model output from each run as follows. For each year of the simulation, PRZM/EXAMS calculates peak (or daily maximum) and time-averaged concentrations. The time-averaged concentrations are calculated by averaging the daily concentrations over five time periods (96-hour, 21-day, 60-day, 90-day, and 1 year). The 90th percentiles over each averaging period are reported as the EECs for that period.

Table 2 Level 1 aquatic ecoscenario modelling results (µg a.i./L) for Dimethoate in water bodies 0.15 m and 0.8 m deep, excluding spray drift.

Region	Schedule	Peak	96 hr	21 d	60 d	90 d	Yearly
15 cm water body depth							
BC	Ornamentals	36	33	25	15	11	3.0
Prairie	Crop	221	203	148	85	64	18.3
Prairie	Ornamentals	874	796	562	314	230	63.5
ON/QC	Crop	364	331	243	159	126	43.5
ON/QC	Ornamentals	765	707	475	248	180	50.6
Atlantic	Crop	86	80	65	38	29	8.2
Atlantic	Ornamentals	1338	1258	965	582	430	117.7
80 cm water body depth							
BC	Ornamentals	7	6	5	3	2	0.6
Prairie	Crop	43	40	30	17	13	3.6
Prairie	Ornamentals	164	152	113	64	46	12.3
ON/QC	Crop	68	63	49	33	26	8.6
ON/QC	Ornamentals	144	135	95	50	36	9.5
Atlantic	Crop	17	16	13	8	6	1.6
Atlantic	Ornamentals	252	241	194	120	88	23.1

2.2 Estimated Concentrations in Drinking Water Sources: Level 1 Modelling

Estimated environmental concentrations (EECs) of Dimethoate in potential drinking water sources (groundwater and surface water) were estimated using computer simulation models. An overview of how the EECs are estimated is provided in the PMRA's Science Policy Notice SPN2004-01, *Estimating the Water Component of a Dietary Exposure Assessment* . EECs of Dimethoate in groundwater were calculated using the LEACHM model to simulate leaching through a layered soil profile over a 50-year period. The concentrations calculated using LEACHM are estimates of the flux, or movement, of pesticide into shallow groundwater (2 m or 5 m depth) with time. EECs of Dimethoate in surface water were calculated using the PRZM/EXAMS models, which simulate pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. Pesticide concentrations in surface water were estimated in two types of vulnerable drinking water sources, a small reservoir and a prairie dugout.

A Level 1 drinking water assessment was conducted using conservative assumptions with respect to application rate and timing, and geographic scenario. The Level 1 EEC estimate is expected to allow for future use expansion into other crops at this application rate. Table 1 lists the application information and main environmental fate characteristics used in the models. Table 3 below provides the Level 1 and Level 2 EECs for potential sources of drinking water.

2.3 Estimated Concentrations in Drinking Water Sources: Level 2 Modelling

Level 2 modelling was performed for surface water, based on the use on potatoes (see Table 1 for use information). Potatoes have the highest application rate of any crop with more than 10 000 ha grown in a region of Canada and therefore are likely to be the largest single crop contributor in any watershed. The level 2 EECs are approximately a factor of six lower than the level 1 EECs resulting from use on ornamentals. It is highly unlikely that ornamentals would cover a significant portion a watershed in comparison with 100% coverage of potatoes within the watershed, and therefore the level 2 EECs listed in Table 3 resulting from use on potatoes are considered to still be conservative. Level 2 modelling was not conducted for groundwater, as the Level 1 EECs for groundwater were orders of magnitude smaller than the surface water EECs.

Table 3 Level 1 and 2 estimated environmental concentrations of Dimethoate in potential drinking water sources

Compound	**Groundwater EEC (µg a.i./L)**		**Surface Water EEC (µg a.i./L)**			
			Reservoir		Dugout	
	Daily[1]	Yearly[2]	Daily[3]	Yearly[4]	Daily[3]	Yearly[4]
level 1	0.01	0.02	210	16	214	16
level 2	not required	not required	35	2.5	45	3.8

[1] 90th percentile of daily average concentrations
[2] 90th percentile of yearly average concentrations
[3] 90th percentile of yearly peak concentrations
[4] 90th percentile of yearly average concentrations

3.0 Water Monitoring Data

3.1 Sources of Data

A search for Dimethoate water monitoring data in Canada resulted in a number of samples with detections being reported. The Federal Provincial and Territorial representatives from all of the provinces and territories in Canada were contacted, requesting water monitoring data for the organophosphates that are currently under re-evaluation. In addition, requests were submitted to Environment Canada, the Department of Fisheries and Oceans and the drinking water subcommittee through Health Canada. A response was received by all provinces and territories indicating that either monitoring data were not available or the available data were submitted.

American databases were searched for detections of Dimethoate. Data on residues present in water samples taken in the United States are important to consider in the Canadian drinking water assessment given the extensive monitoring programs that exist in the US. Runoff events, local use patterns, site specific hydrogeology as well as testing and reporting methods are probably more important influences on residue data rather than Northern versus Southern climate. As for the climate, if temperatures are cooler, residues may break down more slowly, on the other hand if temperatures are warmer, growing seasons may be longer and applications may be more numerous and frequent.

Data were available from the United States Geological Survey National Water Quality Assessment program (NAWQA) for both groundwater and surface water, and from the Six Year Review of National Drinking Water Regulations, as part of the United States National Contaminant Occurrence Database (NCOD).

3.2 Approach for Evaluation

Data from Canadian and American water monitoring studies in which Dimethoate was quantified are summarized in Table 4.

For both the ecoscenario assessment and the drinking water assessment, information was extracted from the available sources, tabulated and sorted into categories as follows:

1. Residues in known drinking water sources (both surface and groundwater)
2. Residues in ambient water that may serve as a drinking water source (both surface and groundwater)
3. Residues in ambient water that are unlikely to serve as a drinking water source

An important limitation of the monitoring data set is that, in many cases, the data were not accompanied with use data for Dimethoate. For instance, the application rate applied, when the application occurred and weather conditions prior to sampling were not known or reported. Without this information, it is difficult to conclude if non-detects were a result of non-transport or more simply a result of inappropriate timing of sampling. In addition, because the data are sparse and concentrations vary in time and space, the maximum concentration reported is unlikely to be the absolute maximum concentration that would be observed in Canada. Factors that may result in higher concentrations being detected include application at higher rates, precipitation and some areas/soils are simply more prone to leaching and/or run off. Sampling at intervals immediately following application would increase the likelihood that the maximum concentration would be detected.

Thus, it is likely Dimethoate was not used in some of the areas monitored, and that higher concentrations of Dimethoate may occur in other areas not monitored. The Dimethoate monitoring data likely underestimate the peak exposure because of the following limitations:

1. In general, the data are sparse in both time and location. In some of the studies available, Dimethoate was analyzed in samples that were taken from non-Dimethoate use areas. Dimethoate use information from the areas surrounding where the samples were collected is often not available.

2. Sampling in some of the studies was conducted during periods when Dimethoate is not applied in Canada (i.e. October through March).

3. The concentrations of organophosphate pesticides in surface water are directly related to the frequency and timing of monitoring in relation to pesticide application and runoff events. Therefore, timing and frequency of sampling is likely to be the most important factor influencing the concentration detected and the frequency of detections. Samples are often taken at arbitrary time intervals (i.e. once a month, once a week) and are unlikely to capture the absolute maximum concentration of Dimethoate.

The following statistics are used to interpret the information available in each dataset and are summarized in Table 4.

- The detection frequency provides an indication of how often positive detections occur within the given data set. Detection frequency is primarily determined by the limits of detection and is influenced by pesticide use patterns and application rates. Consequently, a wide range of detection frequencies is likely to be expected.

- The 95th percentile concentration is calculated and reported. Maximum values should also be considered, especially when the 95th percentile is not available which occurs when there are insufficient detections to calculate a 95th percentile.

- The maximum concentration is reported and is used to determine the 95th percentile concentration to estimate an acute exposure value.

- The arithmetic mean with non-detects considered at ½ LOD is used to determine the 95th percentile concentration to estimate a chronic exposure value. Table 4 Summary of the Monitoring Studies Available

Table 4 Summary of the Monitoring Studies Available

Data Source	**DETECTION FREQUENCY**						**CONCENTRATION PERCENTILES (½ g/L)**		
	Location	**Min detection or detection limit (μg/L)**	**# of systems tested (or absolute number of samples)**	**# of systems or samples with detections**	**% Detection frequency**	**Mean detection**	**95th**	**Absolute Max**	**Arithmetic Mean Including non-detects at ½ LOD**
Dimethoate Residues in Municipal drinking water sources and ground water									
PMRA 1307567	PEI	0.5	12 sa	0	0				
PMRA 1311142, 1311143	Alberta (Treated water)	0.05	1004	0	0				0.025
PMRA 1303805	Saskatchewan (raw and treated water) 1985-1992	0.02	60	0	0				
PMRA 1307578	Apple growing region of Quebec 1994	0.03	42	1sample from one well	2.4 (based on # of wells)			0.07	0.02

Data Source	**DETECTION FREQUENCY**								**CONCENTRATION PERCENTILES (½ g/L)**		
PMRA 1307565	Potato growing region of Quebec			0.03	24 wells	0	0	–	–	–	0.03
PMRA 1311107, 1403269	Drinking water reservoirs - Prairies (2003)			0.025	10 (2 from each of 5 reservoirs)	0	0	–	–	–	0.013
PMRA 1560632, 1640595	New Brunswick Drinking Water supplies (ground and surface water – 2003)		Spring	0.02	7	0	0	–	–	–	0.01
			Summer	0.7	6	0	0	–	–	-	0.35
			Fall	1	6	0	0		–	-	0.5
PMRA 1311119, 1311120	Quebec Groundwater (1999-2001)			0.03	237	0	0			–	0.02
PMRA 1345964	United States water-supply reservoirs	Raw		0.005	323	4	1.3	–	–	0.022	–
		Finished		0.005	228	0	0	–	–	–	
PMRA 1633431	USA			0.0061	2109 sa	0	0	–	–	–	0.003
Dimethoate residues in ambient water that may serve as a drinking water source											
PMRA 1633433	USA			0.01 - 0.003	2434 sa	43 sa	1.7	0.01	0.11	0.16	0.030
PMRA 1307529	Quebec - 1990			0.04	44	0	0	–	–	–	0.020
PMRA 1307576	Lake Ontario 1998-1999			0.001	6	0		–	–	–	0.001
Lake Erie 1994, 1998, 2000	0.001			11	2	18.2		–	0.03	0.001	
Lake Huron 1999, 2000	0.001			7	0	0		–		0.001	
PMRA 1311126	PEI			NR	20	3	15.0			0.033	
PMRA 1307566	PEI			NR	6	3	50	0.03	0.03	0.03	0.015
PMRA 1357366, 1403269	Ontario - Great Lakes area of concern and small streams in Niagara & Burlington (2003)			0.0251	171	18	10.5	0.044	0.086	0.119	0.016
PMRA 1357367, 1403269	Ontario - Great Lakes Area of Concern (2004)			0.0251	225	10	4.4	0.069	0.166	0.175	0.015
PMRA 1357368, 1403269	Ontario - Great Lakes Area of Concern and Connecting Channels (2002)			0.0251	64	6	9.4	0.035	0.046	0.047	0.015
PMRA 1357369, 1403269	Ontario - Lake Huron Tributaries			0.025	37	0	0		–	–	0.012

Data Source	DETECTION FREQUENCY								CONCENTRATION PERCENTILES (½ g/L)		
PMRA 1311104, 1311111, 1311112	British Columbia		0.0006 - 0.0009		6	5	66.7	0.052	0.165	0.193	0.035
PMRA 1307571	Corn and Soya bean region of Quebec	Chibouet	1999	0.03	45	0	0.0			-	0.020
			2000	0.03	40	3	7.5	1.3	0.68	2.6	0.11
			2001	0.03	46	0	0			-	0.02
		Hurons	1999	0.03	45	14	31.1	0.07	0.14	0.19	0.03
			2000	0.03	42	5	12	0.3	0.68	0.7	0.05
			2001	0.03	44	5	11	0.07	0.1	0.11	0.02
		Saint-Regis	1999	0.03	45	1	2.2		-	0.06	0.02
			2000	0.03	43	2	4.7	0.17	-	0.25	0.02
			2001	0.03	45	8	17.8	0.26	0.5	0.53	0.05
		Saint-Zephirin	1999	0.03	45	3	6.7	0.07	0.13	0.14	0.02
			2000	0.03	43	0	0			-	0.02
			2001	0.03	46	0	0			-	0.02
		Yamaska	1999	0.03	45	0	0			-	0.02
			2000	0.03	43	0	0			-	0.02

Data Source	DETECTION FREQUENCY								CONCENTRATION PERCENTILES (½ g/L)		
PMRA 1398451, 1398452, 1398453	Corn and Soya bean region of Quebec	Chibouet	2002	0.04	43	0	0.0				0.020
			2003	0.04	41	0	0			-	0.02
			2004	0.04	41	5	12.2	0.11	0.22	0.34	0.03
		Hurons	2000	0.04	42	1	2.4		-	0.1	0.02
			2003	0.04	41	3	7	0.05	0.06	0.6	0.02
			2004	0.04	41	7	17	1.26	3.4	8.5	0.23
		Saint-Regis	2002	0.04	40	1	2.5		-	0.07	0.02
			2003	0.04	39	3	7.7	0.14	0.2	0.19	0.03
			2004	0.04	39	5	12.8	0.06	0.1	0.12	0.03
		Saint-Zephirin	2000	0.04	42	0	0			-	0.02
			2003	0.04	39	0	0			-	0.02
			2004	0.04	39	4	10.3	0.06	0.07	0.08	0.02
PMRA 1307568	Corn and Soya bean region of Quebec	Chibouet	1996	0.03	40	7	17.5	0.26	0.82	0.96	0.06
			1997	0.03	37	1	2.7		-	0.09	0.02
			1998	0.03	42	0	0			-	0.02
		Hurons	1996	0.03	41	7	17.1	0.06	0.12	0.12	0.02
			1997	0.03	39	7	18	0.06	0.18	0.23	0.02
			1998	0.03	45	5	11	0.12	0.32	0.36	0.03
		Saint-Regis	1996	0.03	41	9	22	0.1	0.2	0.28	0.03
			1997	0.03	40	1	2.5	-	-	0.06	0.02
			1998	0.03	51	0	0	-	-	-	0.02
		Saint-Zephirin	1996	0.03	39	0	0			-	0.02
			1997	0.03	39	0	0				0.02
			1998	0.03	48	0	0			-	0.02

Data Source	DETECTION FREQUENCY							CONCENTRATION PERCENTILES (½ g/L)		
PMRA 1307569	Corn and Soya bean region of Quebec	St. Zephirin	1994	0.015	37	1	2.7		0.02	0.007
			1995	0.015	38	2	5.3	0.03	0.04	0.04	0.007
		Chibouet	1994	0.015	45	1	2.2		-	0.02	0.007
			1995	0.015	38	1	2	0.04	-	0.04	0.007
		des Hurons	1994	0.015	47	12	25.5	0.06	0.13	0.18	0.006
			1995	0.015	34	10	29.4	0.04	0.1	0.1	0.005
		St. Regis	1994	0.015	34	3	8.8	1	2.62	2.9	0.007
			1995	0.015	35	5	14.3	0.1	0.29	0.33	0.006
		St. Esprit	1994	0.015	9	0	0			-	0.008
			1995	0.015	6	2	33.3	0.07	0.12	0.13	0.005
		des Anges	1994	0.015	10	0	0			-	0.008
			1995	0.015	2	0	0			-	0.008
		Bayonne	1994	0.015	9	0	0			-	0.008
		Noire	1994	0.015	6	0	0			-	0.008
		Yamaska	1994	0.015	8	0	0			-	0.008
			1995	0.015	2	0	0			-	0.008
		Nicolet	1994	0.015	4	0	0			-	0.008
		Chateauguay	1994	0.015	1	0	0			-	0.008
PMRA 1307578	Apple Growing Region of Quebec	Deversant	1994	0.03	12	5	41.7	0.26	0.78	0.93	0.12
			1995	0.03	15	4	26.7	0.71	1.94	2.2	0.02
		Boffin	1994	0.03	12	0	0			-	0.015
			1995	0.03	13	0	0			-	0.015
		Abbott's Corner	1995	0.03	12	0	0			-	0.015
PMRA 1307581		Corbin	1996	0.03	17	0	0				0.020
			1997	0.03	34	3	8.8	0.93	1.77	1.9	0.1
		St. Pierre	1996	0.03	1	0	0			-	0.02
		l'Achigan	1996	0.03	18	0	0			-	0.02
			1997	0.03	29	1	3.4		-	0.03	'0.020

Data Source	DETECTION FREQUENCY							CONCENTRATION PERCENTILES (½ g/L)		
PMRA 1307570	Corn growing region of Quebec	Yamaska	1994	0.03	13 sa	0	0				0.020
		Noire Tem	1994	0.03	13sa	0	0		-	-	0.02
		Blanche	1994	0.03	13sa	0	0		-	-	0.02
		St.-Zephirin	1994	0.03	10	0	0		-	-	0.02
			1995	0.03	30	1	3.3		-	0.24	0.02
		St-Germain	1994	0.03	24	0	0		-	-	0.02
			1995	0.03	33	2	6.1		-	0.07	0.02
		Salvail	1994	0.03	24	1	4		-	0.13	0.02
			1995	0.03	33	6	18	0.12	0.17	0.17	0.03
		Chibouet	1994	0.03	23	0	0		-	-	0.02
			1995	0.03	45	2	18.2	0.15	0.2	0.21	0.02
		Des Hurons	1994	0.03	24	4	16.7	0.14	0.25	0.27	0.04
			1995	0.03	44	4	9	0.46	0.98	1.1	0.09
		L'Acadie	1994	0.03	10	0	0		-	-	0.02
			1995	0.03	30	0	0		-	-	0.02
		De La Tortue	1995	0.03	30	2	6.7	0.14	0.18	0.18	0.02
		St-Regis	1995	0.03	30	2	6.7	0.09	-	0.1	0.02
		Des Feves	1995	0.03	26	0	0		-	-	0.02
PMRA 1307585	Alberta		0.05		2038 sa	1 sa	0.05			0.05	0.025
Dimethoate Residues in Water that is unlikely to be used as drinking water sources											
PMRA 1523029	Farm ditches Fraser Valley BC		0.01		43 sa	16	37.2	0.45		11.6	
PMRA 1311123	station d'épuration de Laval (2001)		0.04		25	2	8.0	0.18	0.220	0.23	0.03
	station d'épuration de repentigny (2001)		0.04		27	6	22.2	0.15	0.37	0.44	0.05
	station d'épuration de la CUQ (station est) (2001)		0.04		27	1	3.7			0.13	0.02
	station d'épuration de la CUQ (station ouest) (2001)		0.04		28	4	14.3	0.07	0.090	0.09	0.03
	station d'épuration de Saint-Hyacinthe (2002)		0.04		27	1	3.7			0.22	0.03
	station d'épuration de granby (2002)		0.04		29	0	0				0.02
	station d'épuration de sherbrooke (2002)		0.04		30	2	6.7	1.10	1.370	1.4	0.09
PMRA 1311116, 1403269	Weltands in Prairies (2004)		0.025		8	0	0				0.013
PMRA 1311140	Alberta storm drains (2002)		0.05		39	2	5.1			0.232	0.032

3.3 Ecoscenario Exposure Estimates from Monitoring Data

The acute and chronic exposure estimates for Dimethoate in Canadian surface water are presented in Table 5. The acute exposure value was estimated from monitoring data by determining the 95th percentile of the maximum concentration detected in each monitoring study/site. The chronic exposure value was estimated by determining the 95th percentile of the arithmetic means of all samples at each site (detects and non-detects) from the monitoring studies. The samples with values less than the LOD were given a value of ½ LOD. Groundwater data and data from water distribution systems were not included in the ecoscenario assessment. Uncertainties associated with the data are provided in Section 3.4.1.

Table 5 Concentrations of Dimethoate in Surface Water Estimated from Available Monitoring Data

Acute Concentration (μg/L)*	Chronic Concentration (μg/L)**
2.6	0.09

* 95th percentile of the maximum detected concentrations from surface water monitoring studies

** 95th percentile of the mean concentration for each study site including ½ LOD for non-detects

3.4 Drinking Water Exposure Estimates from Monitoring Data

A search for Dimethoate water monitoring data in Canada and the United States resulted in a number of samples with detections being reported. Details of how the data were handled as well as uncertainties associated with the data are provided in Section 3.4.1. A detailed summary of the Canadian and American water monitoring studies is provided in Table 4. Calculated EECs for acute and chronic exposure from groundwater and surface water are presented in Table 6.

Table 6 Concentrations of Dimethoate in Surface Water Estimated from Available Monitoring Data

Ground Water		Surface Water	
Acute EEC (μg/L)*	Chronic EEC (μg/L)**	Acute EEC (μg/L)*	Chronic EEC (μg/L)**
0.07	0.03	2.3	0.08

* 95th percentile of the maximum detected concentrations from surface water monitoring studies

** 95th percentile of the mean concentration for each study site including ½ LOD for non-detects

4.0 Discussion and Conclusions

4.1 Discussion of Exposure Estimates for Ecoscenario

The concentrations of Dimethoate in wetlands are reported as a range consisting as upper bound and lower bound concentrations rather than a discrete exposure value. The upper bound values are represented as the Level 1 EECs in wetlands, estimated by PRZM-EXAMS for the one-in-ten year exposure (or 90th percentile) (Table 2). These upper bound concentrations represent the highest concentrations of Dimethoate expected in surface water in Canada for the peak, 96-hour, 21-day, 60-day, 90-day, and 1 year time periods. Upper bound concentrations were reported for wetlands 80 cm deep.

The lower end of the range was derived from the available monitoring data on Dimethoate and represents the lowest acute and chronic concentration of Dimethoate in surface water in Canada (Table 5). No time frames other than acute and chronic could be calculated using the monitoring data. No region-specific EECs are provided. The lower bound acute and chronic exposure values were estimated from monitoring data using the 95th percentiles of the maximum and arithmetic mean concentrations (including non-detects) measured in each monitoring study/site, respectively.

The concentrations of Dimethoate detected in water were obtained from studies conducted in various regions across the country. Many of the samples were analyzed in the 1990's and early 2000's. The acute and chronic concentrations predicted by PRZM-EXAMS are higher than those determined by the monitoring data. This is because water monitoring, as conducted in most of the studies reviewed, involves sampling that is limited in time and space and is unlikely to detect the true maximum concentration of the analyte in question. On the other hand, the models predict the concentration expected on a daily basis which allows for the determination of a peak (acute) concentration.

4.2 Drinking Water

Surface Water

The acute concentrations of Dimethoate in surface water are reported as a range consisting of an upper bound and lower bound concentration rather than a discrete exposure value (Table 7). The upper bound value is represented by the Level 1 concentration estimated by PRZM-EXAMS for the one-in-ten year exposure (or 90th percentile). The lower end of the range was derived from the available monitoring data and represents the highest value that the PMRA knows exists in the environment. The lower bound acute exposure value was estimated from monitoring data by determining the 95th percentile of the maximum concentration detected in the monitoring studies. The lower bound chronic exposure value was estimated by determining the 95th percentile of the arithmetic means of all samples at each site (detects and non-detects) from the monitoring studies whose samples were from potential drinking water sources. The samples with values less then the LOD were given a value of ½ LOD.

Given the sparseness of the monitoring data and its limitations as described in Section 3.4.1, Dimethoate exposure could potentially be higher in some areas than indicated by the monitoring data. Thus, modelling results represent a reasonable high-end exposure estimate (Table 7).

Groundwater

The concentration of Dimethoate in groundwater is presented as an upper and lower value using similar logic to that described for surface water (Table 7). Level 2 modelling was not required for groundwater therefore the upper bound value is represented by the Level 1 model value. The Level 1 model results indicate that Dimethoate is likely to be detected in groundwater which is supported by the monitoring data available.

Table 7 Upper and Lower Bound Concentrations Estimated from Models and Monitoring Data

	Groundwater Concentration (µg/L)		Acute Concentration (µg/L)		Chronic Concentration (µg/L)	
	Acute	**Chronic**	**Reservoir**	**Dugout**	**Reservoir**	**Dugout**
Upper Bound[1]	0.01[3]	0.02[4]	35[6]	45[6]	2.5[8]	3.8[8]
Lower Bound[2]	0.07[5]	0.03[5]	2.3[7]		0.05[9]	

[1] From modelling assessment

[2] From monitoring assessment

[3] 90th percentile of daily averages from LEACHM

[4] 90th percentile of yearly average from LEACHM

[5] 95th percentile of the maximum detected concentration from groundwater monitoring studies

[6] 90th percentile of the annual peak concentrations predicted by PRZM-EXAMS at Level 2

[7] 95th percentile of the maximum detected concentrations from surface water monitoring studies

[8] 90th percentile of the annual average concentrations predicted by PRZM-EXAMS at Level 2

[9] 95th percentile of the arithmetic means of all the monitoring studies (includes detects and non-detects)

Conversion of Dimethoate to Omethoate during chlorination of drinking water

EAD and HED have jointly examined available information with respect to the transformation of Dimethoate to Omethoate during treatment of drinking water supplies. The evidence indicates that the formation of Omethoate occurs as a result of oxidation during the chlorination process in water treatment. Based on the available information, the PMRA has assumed 100 percent transformation of Dimethoate to Omethoate, which is consistent with the approach taken by the USEPA. Brief summaries of the studies considered are contained in Appendix X. It is worth noting that the concern for Omethoate formation is restricted to surface water. Public drinking water supplies from groundwater sources are often chlorinated, but they are usually deep wells which are less susceptible to contamination by Dimethoate. Private wells, which tend to be shallow, are more vulnerable to contamination, however, chlorination is seldom used to sanitize private well water.

Appendix XIII Summaries of Studies Reviewed for Oxon Formation During Water Treatment

The effects of drinking water treatment on organophosphate pesticides are discussed in two EPA documents:

- USEPA, Revised OP Cumulative Risk Assessment, 6/11/02. Appendix E, Water Appendix, Part 4: Effects of Drinking Water Treatment on Organophosphate Pesticides. Accessed at: http://www.epa.gov/oppsrrd1/cumulative/rra-op/III_E_WaterAppendix/III_E_4.pdf

This appendix provides a critical review of data used by USEPA to assess the effects of water treatment on transformation of organophosphorous pesticides. The review indicates that OP pesticides are transformed in chlorinated drinking water. Chemical oxidation of the organophosphorus compounds led to the formation of oxons for azinphos-methyl, chlorpyrifos, diazinon, and malathion. The oxons were more stable than their parent organophosphorus pesticides, and degradation of oxons was attributed to non-chlorine degradation processes and/or hydrolysis.

- USEPA, Revised OP Cumulative Risk Assessment, 6/11/02. Appendix E, Water Appendix, Part 3: Water Exposure Assessment, Preliminary Analysis of the USGS-EPA Pilot Reservoir Monitoring Program. Accessed at: http://www.epa.gov/oppsrrd1/cumulative/pra-op/iii_e_3-f.pdf

The USEPA conducted a pilot reservoir monitoring project that measured pesticide concentrations in raw and finished drinking water. Several organophosphorous pesticides and their transformation products were included in the study. The data indicate that the concentrations of most parent OPs were reduced to below the detection limit during water treatment, and that oxidative transformation products were detected in the finished water. Table III.E.3.9 reports estimates of water treatment reduction factors for selected OPs, and these range up to 97% for malathion and was reported to be 88% for Dimethoate. The report cautions that individual water treatment processes can vary widely, and thus it is difficult to assess the impact of specific water treatment processes on pesticide removal and transformation. Dimethoate was analyzed for in only two reservoirs and was detected in both. The oxon transformation product for Dimethoate (Omethoate) was not analyzed for in this study therefore, it is difficult to evaluate the linkage between Dimethoate transformation and Omethoate formation in finished water samples. However, there were three samples in which malathion was found in raw water and malaoxon was found in finished water.

- Tienry, D.P., B.R. Christrensen, and V.C. Culpeppeter. 2001. Chlorine Degradation of Six Organophosphorus Insecticides and Four Oxons in Drinking Water Matrix. Submitted by Syngenta Crop Protection, Inc. Greensboro, N.C. Performed by Syngenta Crop Protection, En-fate, LLC., and EASI Laboratory.

The USEPA assessment of the exposure due to Dimethoate residues in drinking water, 2nd revision indicated that this study showed relatively complete conversion of the part to the oxon transformation product during the chlorination phase of drinking water treatment.

HED to add additional information once the study is received in PMRA.

- Biological and Economic Analysis Division. 2005. Results of Studies of the Chlorination of Dimethoate and Malathion and stability Characterization of the Oxygen Analogs, Omethoate and Malaoxon in Chlorinated Water. Office of Pesticide Programs. Washington, DC.

The USEPA assessment of exposure due to Dimethoate residues in drinking water, 2nd revision summarized this study. The data from this study indicate that 1) Omethoate forms from Dimethoate by chlorination during drinking water treatment and 2) the conversion rate is *at least* 20%. While that data for Dimethoate/Omethoate appear to be sound, there are unresolved analytical chemistry issues for this study relating to malathion/malaoxon. Since these issues raise concerns about the same methods as used for Dimethoate/Omethoate, the study authors recommend only using the results qualitatively at this time. When the analytical issues are resolved for this study the PMRA will consider more quantitative use of this data if the issues are resolved satisfactorily.

References

Chemistry

Studies/Info Provided by the Registrant

PMRA 1649491 Chemistry data used to support a Technical class product. DIM-CNV-1, DACO 2.13.4

PMRA 1649493 1997, Specification Dimethoate Technical Analysis of 5 Typical Batches of Dimethoate Technical, DACO 2.13.3

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